MAMMOGRAPHY PROGRAM STANDARDS

1. SUMMARY OF MAJOR CHANGES: This revised Veterans Health Administration (VHA) directive updates implementation instructions and procedures for the establishment, sitting, administration, accreditation, certification, staffing, and performance of mammography programs in Department of Veterans Affairs (VA) medical facilities, including those managed by VHA, community-based outpatient clinics (CBOCs), and leased facilities. This VHA directive:

a. Updates the Responsibilities paragraph (see paragraph 2).

b. Updates the Responsibility paragraph for the Lead Interpreting Physician (IP) to conduct on-premises regular site reviews, at a minimum of twice annually, for all programs where the individual is listed as the Lead IP.

c. Updates requirements for screening mammogram report turnaround time.

d. Updates directive to reflect VA's transition to a new electronic health record (EHR) and to enable implementation of this directive at VA medical facilities using the Oracle Health EHR.

e. Updates signature authority for VHA mammography program certification to the Executive Director, National Radiology Program.

f. Adds the requirement for the VA medical facility IP to be onsite during the performance of diagnostic mammography and diagnostic breast ultrasound.

g. Removes the requirement to develop a local policy related to quality, patient education, effective and clear communication with patients, clear communication of mammography results, infection control, and safety.

2. RELATED ISSUES: VHA Directive 1330.01(7), Health Care Services for Women Veterans; dated February 15, 2017; VHA Directive 1088, Communicating Test Results to Providers and Patients, dated July 11, 2023; VHA Directive 1043, Restructuring of VHA Clinical Programs, dated November 2, 2016; and VHA Directive 1104, Picture Archiving and Communications, dated September 1, 2017.

3. POLICY OWNER: The Executive Director, National Radiology Program, Diagnostic Services (11DIAG1), is responsible for the contents of this directive. Questions may be referred to VHARadiologyProgramOffice@va.gov.

4. LOCAL DOCUMENT REQUIREMENTS: VA medical facilities are required to develop and maintain VA medical facility standard operating procedures for consumer (patient) complaints, infection control, quality control and assurance, enhancing quality

using the inspection program (EQUIP), breast imaging results communication, and examination protocols (see paragraph 2.k.(2) and 2.m.(12)).

5. RESCISSIONS: VHA Directive 1105.03, Mammography Program Procedures and Standards, dated May 21, 2018, is rescinded.

6. IMPLEMENTATION SCHEDULE: This policy is effective 3 months from the date of publication.

7. RECERTIFICATION: This VHA directive is scheduled for recertification on or before the last working day of May 2029. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

BY DIRECTION OF THE OFFICE OF THE UNDER SECRETARY FOR HEALTH:

/s/ Erica Scavella, M.D., FACP, FACHE
Assistant Under Secretary for Health for Clinical Services and Chief Medical Officer

NOTE: *All references herein to VA and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.*

DISTRIBUTION: Emailed to the VHA Publications Distribution List on May 22, 2024.

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MAMMOGRAPHY PROGRAM STANDARDS

MAMMOGRAPHY PROGRAM STANDARDS

1. POLICY

It is Veterans Health Administration (VHA) policy that the certification, staffing, and functioning of mammography programs in Department of Veterans Affairs (VA) medical facilities, facilities managed by VHA, and community-based outpatient clinics (CBOCs) or leased facilities; and care coordination in the community of reports and images from outsourced mammography exams are managed safely, timely, and accurately.
AUTHORITY: 38 U.S.C. §§ 7301(b), 7319, 7322.

2. RESPONSIBILITIES

a. **Under Secretary for Health.** The Under Secretary for Health is responsible for:

(1) Ensuring overall VHA compliance with this directive.

(2) Ruling on appeals of mammography certification decisions made by the Executive Director, National Radiology Program (NRP).

b. **Assistant Under Secretary for Health for Clinical Services.** The Assistant Under Secretary for Health for Clinical Services is responsible for:

(1) Supporting NRP and Diagnostic Services with appropriate implementation and oversight of this directive.

(2) Providing resources for the operation and oversight of mammography program responsibilities.

c. **Assistant Under Secretary for Health for Operations.** The Assistant Under Secretary for Health for Operations is responsible for:

(1) Communicating the contents of this directive to each of the Veterans Integrated Service Networks (VISNs).

(2) Assisting VISN Directors to resolve implementation and compliance challenges in all VA medical facilities within that VISN.

(3) Providing oversight of VISNs to ensure compliance with this directive and its effectiveness.

d. **Executive Director, Diagnostic Services.** The Executive Director, Diagnostic Services is responsible for:

(1) Supporting NRP with policy development and oversight of requirements of this directive.

(2) Supporting VISN Directors with implementation and compliance with this directive.

e. **Executive Director, National Radiology Program.** The Executive Director, NRP is responsible for:

(1) Providing oversight, certification, and enforcement of VHA mammography programs, policies, and standards.

(2) Approving initiation and closure of corrective action plans to obtain or maintain VHA certification and ensure that a high standard of service and patient care is provided.

(3) Approving the conduct of ad hoc and for cause on-site or virtual program reviews to address new program activation, accreditation, certification, quality, safety, or regulatory concerns.

(4) Providing feedback to VISN Diagnostic Integrated Clinical Communities and VISN and VA medical facility leadership regarding compliance, safety, quality, and access for breast imaging services.

(5) Ensuring that all VHA mammography programs maintain accreditation with the American College of Radiology (ACR) as a condition of certification.

(6) Ensuring that all on-site mammography programs obtain certification (interim, provisional) prior to patient imaging through the NRP certification process.

(7) Approving full or provisional certification or the denial, renewal, extension, suspension, or revocation of VHA mammography program certification.

(8) Suspending or revoking the certification of VHA mammography programs that do not maintain ACR accreditation, or do not meet the mammography standards of 21 C.F.R. Part 900, or programs that have demonstrated ongoing or uncorrected deficiencies, safety, or quality concerns.

(9) Reviewing and ruling on first level appeals of denial, suspension, revocation, or other certification action.

f. **Assistant Director, National Radiology Program.** The Assistant Director, NRP is responsible for:

(1) Assisting the Executive Director, NRP, with all aspects of compliance with this directive.

(2) Ensuring that the resources of the NRP are used effectively and efficiently to support the requirements and initiatives of VHA breast imaging programs.

g. **Breast Imaging Operations Director.** The Breast Imaging Operations Director is responsible for:

(1) Providing recommendations and guidance to the Executive Director, NRP, concerning certification (full or provisional approval, denial, renewal, extension, suspension, or revocation of certification) for VHA mammography programs that do not maintain ACR accreditation or do not meet the mammography standards of 21 C.F.R. Part 900 or programs that have demonstrated ongoing or uncorrected deficiencies, safety, or quality concerns.

(2) Providing mammography inspection and accreditation results to National Radiology leadership, VISN clinical leadership, and individual facilities for use in program improvement, compliance, and oversight activities.

(3) Interpreting regulatory requirements found in Federal statutes, standards, and guidance pertaining to mammography quality standards and conduct of mammography programs.

(4) Making recommendations to the Executive Director, NRP, to initiate ad hoc and for cause on-site or virtual program reviews, as appropriate, of VHA mammography programs to address issues of accreditation, certification, quality, safety, or regulatory concerns, including recommendations regarding the implementation of corrective action by a VHA mammography program as necessary to obtain or maintain VHA certification to ensure that a high standard of service and patient care is provided.

(5) Conducting ad hoc and for cause site visits, virtual audits, or similar activities to review new or existing VHA mammography programs, ensure performance and maintenance of corrective actions, ensure compliance with accrediting body (AB) requirements and inspection recommendations, and to perform oversight of VHA policy, safety, and quality standards by VHA mammography programs.

h. **Veterans Integrated Service Network Director.** VISN Directors are responsible for ensuring that all VA medical facilities within the VISN comply with this directive and have sufficient resources to comply with this directive.

i. **VA Medical Facility Director.** The VA medical facility Director is responsible for:

(1) Ensuring facility compliance with this directive and that appropriate corrective action is taken if non-compliance is identified.

(2) Ensuring that the facility mammography program develops and maintains standard program elements in accordance with standard operating procedure (SOP) 01: Mammography Program Requirements located on the National Radiology Program's SharePoint site at https://dvagov.sharepoint.com/sites/VHADiagnosticservices/Mammography/SitePages/VHA-Directive-1105.03.aspx. ***NOTE:*** *This is an internal VA website that is not available to the public.*

(3) Ensuring that the VA medical facility provides timely notification of all breast imaging results (including mammography, breast ultrasound, breast magnetic resonance imaging (MRI), or other breast imaging modality) to the ordering VA health

care provider and to the patient, whether performed at a facility mammography program or in the community through Integrated Veterans Care (IVC), in accordance with SOP 7: Patient Reports and Records Management located on the National Radiology SharePoint site at https://dvagov.sharepoint.com/sites/VHADiagnosticservices/Mammography/SitePages/VHA-Directive-1105.03.aspx. ***NOTE:*** *This is an internal VA website that is not available to the public.*

(4) Ensuring that the VA medical facility provides tracking and timely follow-up of findings from breast screening and diagnostic exams (including mammography, ultrasound, MRI, or other breast imaging modality), whether performed at a facility mammography program or through care in the community. This includes establishing processes and responsibilities for entry of breast imaging codes into the EHR so this data may be incorporated into the Office of Women's Health Breast Care Registry. See SOP 7: Patient Reports and Records Management located on the Radiology SharePoint site at https://dvagov.sharepoint.com/sites/VHADiagnosticservices/Mammography/SitePages/VHA-Directive-1105.03.aspx. ***NOTE:*** *This is an internal VA website that is not available to the public.*

(5) Supporting continuous accreditation and VHA certification to perform mammography services for all VA medical facility in-house mammography programs.

(6) Ensuring that there are sufficient resources for facility mammography programs, including space and equipment, as well as radiologist, technologist, and support staffing to provide high-quality breast imaging services.

(7) Collaborating and coordinating with NRP to facilitate program reviews and site visits as required by Executive Director, NRP, to address issues of accreditation, certification, quality, safety, or regulatory concerns, including requiring implementation of corrective action as necessary to obtain or maintain VHA certification or to ensure that a high standard of quality and service is provided.

(8) For sites using the Oracle Health EHR, ensuring completion of EHR PowerForm, to enter mammography results received from community care providers.

(9) Ensuring that all on-site mammography program staff, including the Lead IP, IP and mammography technologist(s), and inclusive of contract staff, comply with the requirements of this directive.

(10) Ensuring the availability of a board-certified physicist, VHA staff or contractor, to meet the requirements of this directive.

(11) Submitting data from ACR and the Food and Drug Administration (FDA) Mammography Quality Standards Act (MQSA) inspections to NRP, in accordance with SOP 4: Food Drug Administration Mammography Quality Standards (MQSA) Inspections located on the Radiology SharePoint site at https://dvagov.sharepoint.com/sites/VHADiagnosticservices/Mammography/SitePages/

VHA-Directive-1105.03.aspx. ***NOTE:*** *This is an internal VA website that is not available to the public.*

(12) Ensuring that a commercial off-the-shelf electronic mammography report tracking system is in use at all VHA on-site mammography programs within 1 year from the date of this directive.

(13) Ensuring that future new or replacement installation of a commercial mammography tracking system is done as a collaborative effort with other VISN mammography programs or the National Teleradiology Program.

(14) Ensuring that contracts for VA medical facility medical physicists, Lead IPs, IPs, and technologists who participate in the mammography program conform to the requirements of this directive.

j. **VA Medical Facility Chief of Staff.** The VA medical facility Chief of Staff is responsible for

(1) Assisting VA medical facility Radiology Service Chiefs with compliance with this directive.

(2) Reviewing at least quarterly the staffing recommendations as reported by the VA medical facility Radiology Service Chief and the contract Contracting Officer Representative (COR) for individuals assigned quality assurance (QA) tasks to ensure they are qualified to perform these tasks and that their performance is acceptable.

k. **VA Medical Facility Radiology Service Chief.** The VA medical facility Radiology Service Chief is responsible for:

(1) Overseeing the VA medical facility mammography program conduct and compliance with 21 C.F.R. Part 900.

(2) Developing SOPs for consumer (patient) complaints, infection control, quality control (QC) and assurance, enhancing quality using the inspection program (EQUIP), breast imaging results communication, and examination protocols in accordance with SOP 8: Quality Control and Quality Assurance Programs located on the National Radiology SharePoint site at https://dvagov.sharepoint.com/sites/VHADiagnosticservices/Mammography/SitePages/VHA-Directive-1105.03.aspx. The SOPs must be current, reflect actual practice and be readily available to mammography program staff, in accordance with SOP 1: Mammography Program Elements located on the National Radiology SharePoint site at https://dvagov.sharepoint.com/sites/VHADiagnosticservices/Mammography/SitePages/VHA-Directive-1105.03.aspx. ***NOTE:*** *This is an internal VA website that is not available to the public.*

(3) Ensuring development and maintenance of a mammography QA program. ***NOTE:*** *The mammography QA program and each of its elements must only be*

assigned to individuals who are qualified for their assignments and who are allowed adequate time and resources to perform these duties.

(4) Ensuring that QA monitors are reported to the radiology VA medical facility quality improvement committee at periodic intervals, at least quarterly.

(5) Ensuring that the VA medical facility Radiology Department Quality Improvement Committee reports periodically, at least quarterly, to a facility-level committee which allows oversight by the VA medical facility medical staff and VA medical facility executive senior leadership in accordance with existing facility reporting structure. Examples include but are not limited to the Medical Executive Committee, Quality, Safety and Value Committee and the Environment of Care Committee.

(6) Ensuring that all display monitors used in the interpretation of mammography and all printers used by the program are FDA-approved and comply with a QA program that is substantially the same as that recommended by the manufacturer and pass the ACR phantom and clinical image review process.

(7) Ensuring that each diagnostic mammogram and diagnostic breast ultrasound performed at the VA medical facility is performed under the direct supervision of an on-site IP. Diagnostic mammography may require the IP to actively integrate mammographic findings with other breast imaging modalities (e.g., ultrasound, MRI) and physical examination to evaluate abnormalities or suspected abnormalities of the breast. This also provides the opportunity to engage the patient and provide immediate communication of results. Screening breast ultrasounds may be performed without an onsite IP. Any call back ultrasound, however, must be performed with the IP on site. ***NOTE:*** *For sites where this requirement is not feasible or there are no viable options for care in the community, a time limited waiver request may be submitted through facility and VISN leadership to NRP for consideration.*

(8) Ensuring medical physicist evaluation of mammography equipment is performed once every year and after equipment (including both mammography imaging equipment and medical image displays and workstations) moves, major equipment repairs, and for new equipment placed into service, as set forth in 21 C.F.R. § 900.12.

(9) For mammography programs with VHA IPs:

(a) Designating a VA medical facility Lead IP.

(b) Coordinating the functions of the program based on the mission, special needs, and size of the facility. ***NOTE:*** *This responsibility may be delegated as appropriate to the VA medical facility Lead IP.*

(c) Maintaining a list of names of all program personnel with delegated QA responsibilities for the VA medical facility, including the Lead IP, medical physicists, QC technologists, and Audit IPs.

(d) Issuing a statement of responsibilities. ***NOTE:*** *Because the standards, 21 C.F.R. § 900.12, already specify the responsibilities of the VA medical facility Lead IP, medical physicists, QC technologists and Audit IPs, the VA medical facility does not have to restate the responsibilities of the program individuals. However, if the VA medical facility delegates QA responsibilities to someone other than the VA medical facility Lead IP, medical physicists, QC technologists, or Audit IPs, a statement of responsibilities and the credentials for such individual(s) must be provided.*

(e) Providing support for the VA medical facility Lead IP to comply with the requirements of this directive, including the requirement for on-premises at minimum quarterly audits at all separate points of care within the VA medical facility's mammography program(s). ***NOTE:*** *The quarterly on-premises audit requirement may be reduced to twice a year if the program utilizes an electronic system for QA/QC that gives the Lead IP real time access to QC data.*

(10) For mammography programs with VA-contracted IP staff:

(a) Ensuring that the contract requires compliance with this VHA directive and 21 C.F.R. Part 900.

(b) Ensuring designation of a Lead IP.

(c) Ensuring the names of the Lead IP, medical physicists, QC technologists, Audit IPs and any other program personnel with delegated QA responsibilities are placed in writing and accessible to all VA-employed and VA-contracted personnel. All changes to this staff roster must be made within 1 business day of designation by or becoming known to the VA medical facility Radiology Service Chief. ***NOTE:*** *For all contracted staff, the COR must notify the Radiology Service Chief of any changes in personnel within 1 business day.*

(d) Ensuring that if the program delegates QA responsibilities to someone other than the Lead IP, medical physicists, QC technologists, or Audit IPs, a statement of responsibilities for such individual(s) and their credentials are provided and maintained.

(11) Reporting to the VA medical facility Chief of Staff at periodic intervals (at least quarterly) on the staffing recommendations received by the VA-contracted Lead IPs to be included in the Quality Assurance Surveillance Plan (QASP).

l. **Chair, VA Medical Facility Radiology Department Quality Improvement Committee.** The Chair, VA Medical Facility Radiology Department Quality Improvement Committee is responsible for reporting periodically, at least quarterly, to a facility level committee which allows oversight by the VA medical facility medical staff and VA medical facility executive senior leadership in accordance with existing facility reporting structure. Examples include but are not limited to the Medical Executive Committee, Quality, Safety and Value Committee and the Environment of Care Committee.

m. **VA Medical Facility Mammography Program Lead Interpreting Physician.** ***NOTE:*** *The Lead IP is an IP assigned the general responsibility for ensuring that a*

facility's mammography QA program meets all requirements. The administrative title and other supervisory responsibilities of the individual, if any, are left to the discretion of the VA medical facility. The VA medical facility mammography program Lead IP must be a mammography-qualified IP and is responsible for:

(1) Overseeing the VA medical facility on-site mammography program daily operations, compliance, and safety.

(2) Ensuring implementation and providing oversight of program conduct of FDAs EQUIP.

(3) Ensuring the conduct of site reviews for evaluation of the environment of care and for review of QA/QC data for all mammography programs within their purview.

(a) Ensuring that an environment of care review is conducted at least quarterly, and personally conducting an environment of care review at least twice annually on premises. The Lead IP may delegate up to two quarterly reviews to a member of the mammography staff but remains responsible for the conduct and content of the review.

(b) Review of mammography program QA/QC data must be performed at a minimum quarterly by the Lead IP.

(4) Ensuring that the QA program, including personnel assignments, retention and release of personnel records, all equipment QC tests, records, corrective actions, the annual physicist's survey, and medical audit for both screening and diagnostic programs, and outcome analysis, meets the required standards in VHA policy, ACR accreditation and FDA MQSA regulations. See Mammography Program SOPs (1-11) located on the National Radiology Program SharePoint site at https://dvagov.sharepoint.com/sites/VHADiagnosticservices/Mammography/SitePages/VHA-Directive-1105.03.aspx. ***NOTE:*** *This is an internal VA website that is not available to the public.*

(5) Ensuring that the individuals assigned QA tasks are qualified to perform these tasks and that their performance is acceptable. ***NOTE:*** *VHA contracts must require VA-contracted Lead IPs to make these staffing recommendations to the VA medical facility Radiology Service Chief to be included in the QASP (or equivalent) which must be reported by the VA medical facility Radiology Service Chief to the VA medical facility Chief of Staff for review at periodic intervals, at least quarterly.*

(6) Reviewing and discussing medical outcome audits with the IP or assigning this task to another IP (such as the Audit IP). ***NOTE:*** *The responsibilities of the Audit IP, who must also be a qualified IP, must be consistent with 21 C.F.R. § 900.12(f)(3). For programs with only one IP, that person will be the Lead IP.*

(7) Participating in the 3-year accreditation renewal process, the annual FDA inspection, and any other review of mammography quality within the program.

(8) Designating a Lead Mammography Quality Control (LMQC) technologist who meets the mammography technologist requirements, and who is responsible for those QA responsibilities not assigned to the Lead IP or to the medical physicist. ***NOTE:*** *VHA contracts must require VA-contracted Lead IPs to make recommendations for designation to the VA medical facility Radiology Service Chief.*

(9) Being directly involved in the selection of a qualified medical physicist, to, at a minimum, survey the mammography equipment once every year, see SOP 6: Medical Physicist Surveys located on the National Radiology Program SharePoint site at https://dvagov.sharepoint.com/sites/VHADiagnosticservices/Mammography/SitePages/VHA-Directive-1105.03.aspx. ***NOTE:*** *VHA contracts must require VA-contracted Lead IPs to make recommendations to the VA medical facility Radiology Service Chief. This is an internal VA website that is not available to the public.*

(10) Assisting with any program reviews as conducted or sanctioned by the Executive Director, NRP, as requested or required.

(11) Establishing a contingency plan for the performance of required QC activities to ensure compliance with QC requirements during planned and unplanned absence of the VA medical facility LMQC Technologist.

(12) Assisting the Radiology Service Chief in development of a comprehensive SOP for consumer (patient) complaints, infection control, QC and assurance, EQUIP, breast imaging results communication, and examination protocols.

n. **VA Medical Facility Mammography Program Audit Interpreting Physician.** The VA medical facility mammography program Audit IP is responsible for:

(1) Conducting and reviewing medical outcomes audit data at least once every 12 months.

(2) Recording the dates of the medical outcomes audit period(s) and analyzing results.

(3) Documenting medical outcomes audit results and for notifying other IPs of their results and the facility aggregate results.

(4) Documenting follow up actions, if follow up actions are taken, the Audit IP will also be responsible for documenting the nature of the follow up.

o. **VA Medical Facility Mammography Program Interpreting Physician.** The VA medical facility mammography program IP is responsible for:

(1) Consulting with referring clinicians regarding the medical significance of breast image findings and reports.

(2) Being present on-site and immediately available to supervise and assist the mammography technologist throughout the performance of diagnostic mammography

and breast ultrasound. The IP must be present on the same campus and immediately available and interruptible to furnish assistance and direction throughout the performance of a diagnostic mammogram. ***NOTE:*** *For sites where this requirement is not feasible, a time limited waiver request may be submitted through facility and VISN leadership to NRP for consideration. For all waivers of on- site presence of the mammographer, the requirement for real time consultation with the mammography technologist must remain for all diagnostic breast imaging examinations.*

(3) Evaluating the quality of the mammography images they interpret and the content of the reports they verify.

(4) Providing frequent and consistent feedback to the Lead IP and mammography technologist, according to facility and radiology service practices, concerning the images they interpret.

(a) Recognizing, reinforcing, and rewarding high-quality images and QC practices.

(b) Identifying and providing feedback to VA medical facility mammography technologists for the improvement of poor quality image technique, as image quality affects the detection of potential breast cancers and treatment planning.

(5) Participating in the VA medical facility's mammography medical outcomes audit program.

(6) Complying with processes for reporting and the assignment of diagnostic codes, see the SOP 7: Patient Reports and Records Management located on the National Radiology Program SharePoint site at https://dvagov.sharepoint.com/sites/VHADiagnosticservices/Mammography/SitePages/VHA-Directive-1105.03.aspx. ***NOTE:*** *This is an internal VA website that is not available to the public.*

(7) Complying with the process requirements for communicating results to patients and ordering providers as outlined in the SOP 7: Patient Reports and Records Management, SOP 9: BI-RADS Assessment Category Language and SOP 10: Breast Tissue Composition located on the National Radiology SharePoint site at https://dvagov.sharepoint.com/sites/VHADiagnosticservices/Mammography/SitePages/VHA-Directive-1105.03.aspx. ***NOTE:*** *This is an internal VA website that is not available to the public.*

p. **VA Medical Facility Mammography Program Medical Physicist.** The VA medical facility mammography program Medical Physicist is responsible for:

(1) Evaluating mammography equipment annually and following equipment moves, major equipment repairs, and for new equipment placed into service, as set forth in 21 C.F.R. § 900.12(e). Mammography equipment is inclusive of mammography image capture devices and components as well as medical image displays and workstations.

(2) Ensuring that the mammography program annual survey includes all QC tests specified in 21 C.F.R. § 900.12, the phantom image quality test, other (including new) mammographic modality tests, as well as an evaluation of the QC tests and results that are normally conducted by the QC technologist.

(3) Providing the program with a report of the annual survey within 5 business days. If there is a "failed" test, the mammography program must be notified at the time of the survey.

(4) Assisting program staff as needed to assure proper performance of the mammography equipment.

q. **VA Medical Facility Lead Mammography Quality Control Technologist.** The VA medical facility LMQC Technologist is responsible for:

(1) Performing QA and QC duties as assigned by the VA medical facility Lead IP. ***NOTE:*** *For programs with only one mammography technologist, that person will be the LMQC technologist. Normally, the LMQC technologist is expected to perform the QC duties, but other qualified technologist may be assigned or trained to do some or all of the tests. When these duties are assigned to others, the LMQC technologist retains the responsibility to ensure they are performed in accordance with applicable standards. FDA recommends having a single VA medical facility LMQC technologist. FDA has found this to be a best practice with less fragmentation that generally allows for better management of the mammography program with more consistent results.*

(2) Notifying program staff of new mammography standards and modifications to existing mammography standards and of guidance authored by VHA, FDA, or ACR.

(3) Acting as a QC resource to the VA medical facility Lead IP.

(4) Ensuring the program has VHA/FDA required SOPs available. See the SOP 5: Mammography Program Documents Management located on the National Radiology Program SharePoint site at https://dvagov.sharepoint.com/sites/VHADiagnosticservices/Mammography/SitePages/VHA-Directive-1105.03.aspx. ***NOTE:*** *This is an internal VA website that is not available to the public.*

(5) Ensuring all assigned QA and QC tasks are completed and documented and retained in compliance with VHA policy and FDA standards and requirements.

(6) Being the point of contact for FDA mammography standards inspections in the absence of, or as a designee of, the VA medical facility Radiology Service Chief or Lead IP.

(7) Analyzing inspection reports of the program to identify problems and trends, and reporting this information to the Lead IP, VA medical facility Radiology Service Chief, and appropriate facility management.

(8) Providing input, as appropriate, to correct deficiencies noted during inspections and to ensure that the noted deficiencies are addressed appropriately to ensure correction and compliance.

(9) Reviewing QA and QC reports from the VHA Mammography Program, FDA, ACR, Office of the Inspector General (OIG), Office of the Medical Inspector (OMI), or other VA-authorized body dealing with the mammography program and following up with the VA medical facility Lead IP and Radiology Service Chief to ensure that issues identified in these reports are addressed and corrected as specified in the reports.

(10) Advising the VA medical facility Lead IP and Radiology Service Chief of problems and concerns affecting the quality of the work in the program.

(11) Assisting the Lead IP in ensuring that the program complies with the inspection and accreditation requirements set forth by VHA policies, ACR, and FDA. (See paragraph 2.l.(3).) See SOP 2: Accreditation and Certification and SOP 3: Mammography Accreditation Denial located on the National Radiology Program SharePoint site at https://dvagov.sharepoint.com/sites/VHADiagnosticservices/Mammography/SitePages/VHA-Directive-1105.03.aspx. ***NOTE:*** *This is an internal VA website that is not available to the public.*

(12) Reviewing records in accordance with instructions located in Mammography Program Documents Management, see the SOP 5: Mammography Program Documents Management located on the Radiology SharePoint site at https://dvagov.sharepoint.com/sites/VHADiagnosticservices/Mammography/SitePages/VHA-Directive-1105.03.aspx. ***NOTE:*** *This is an internal VA website that is not available to the public.*

r. **VA Medical Facility Mammography Technologist.** The VA medical facility Mammography Technologist is responsible for:

(1) Patient care and image quality, including patient positioning, breast compression, image acquisition, infection control.

(2) Documenting QC procedures and data in accordance with local departmental procedures. Examples include use of: (1) paper binder, (2) SharePoint or share drive, or (3) commercial quality control software.

(3) Participating in the EQUIP program.

(4) Complying with data entry and tracking of patients in the mammography program electronic breast imaging tracking system.

(5) Maintaining records of clinical experience to ensure compliance with regulatory volume standards.

s. **VA Medical Facility Contracting Officer Representative.** The VA medical facility COR is responsible for notifying the Radiology Service Chief of any changes in contracted staff within 1 business day for all contracted staff.

3. TRAINING

There are no formal training requirements associated with this directive.

4. RECORDS MANAGEMENT

All records regardless of format (for example, paper, electronic, electronic systems) created by this directive must be managed as required by the National Archives and Records Administration (NARA) approved records schedules found in VHA Records Control Schedule 10-1. Questions regarding any aspect of records management can be addressed to the appropriate Records Officer.

5. BACKGROUND

VHA has provided routine mammography to Veterans since 1983. VHA mammography programs range in complexity and configuration from comprehensive on-site programs that provide breast screening, diagnostic mammography and interventional procedures, to programs that provide limited services, such as breast screening exams only. VHA National Center for Health Promotion and Disease Prevention (NCP) establishes guidelines for breast cancer screening. VA medical facilities adhere to the FDA regulations established by the MQSA, 21 C.F.R Part 900. Section 7319(b) of 38 U.S.C. requires VA to prescribe quality assurance and QC standards relating to the performance and interpretation of mammograms and the use of mammogram equipment at VA medical facilities consistent with the requirements of section 354(f)(1) of the Public Health Service Act (42 U.S.C. § 263b). Such standards must be no less stringent than the standards prescribed by the Secretary of Health and Human Services under section 354(f) of the Public Health Service Act.

6. DEFINITIONS

a. **Accrediting Body.** For purposes of this directive, an AB is a private, non-profit entity approved by FDA under 21 C.F.R. § 900.3(d) to accredit mammography facilities.

b. **Audit Interpreting Physician.** An Audit IP is a mammography qualified IP, listed as an IP in the mammography program, and designated to review the medical outcomes audit data at least once every 12 months.

c. **Diagnostic Mammogram.** A diagnostic mammogram is a mammogram performed for evaluation of patients that have clinical signs or symptoms of breast disease, or if a radiologist detects findings of concern on a screening mammogram and orders additional mammographic views or short-term follow-up exams.

d. **Digital Breast Tomosynthesis.** Digital breast tomosynthesis (DBT) is a 3-dimensional (3-D) mammogram that involves acquiring images of a stationary

compressed breast at multiple angles during a short scan. The individual images are then reconstructed into a series of thin high-resolution slices that are displayed individually or in a dynamic ciné mode.

e. **Electronic Health Record.** Electronic Health Record (EHR) is the digital collection of patient health information resulting from clinical patient care, medical testing, and other care-related activities. Authorized VA health care providers may access EHR to facilitate and document medical care. EHR comprises existing and forthcoming VA software including Computerized Patient Record System (CPRS), Veterans Information Systems and Technology Architecture (VistA), and Oracle Health platforms. ***NOTE****: The purpose of this definition is to adopt a short, general term (EHR) to use in VHA national policy in place of software-specific terms while VA transitions platforms.*

f. **Full Field Digital Mammography.** Full field digital mammography (FFDM) is a method for breast radiography using low energy x-rays recorded by an electronic digital detector instead of film. This electronic image can be displayed on a video monitor. The radiologist can manipulate the digital mammogram electronically to magnify an area, change contrast, or alter the brightness.

g. **Interpreting Physician.** For purposes of this directive, an IP is a physician who is qualified to independently interpret mammograms by meeting MQSA requirements.

h. **Lay Summary Letter.** A lay summary letter is a summary of the written mammography report that is given or sent directly to the patient in terms easily understood by a lay (non-medical) person.

i. **Lead Interpreting Physician.** The Lead IP is an IP assigned the general responsibility for ensuring that a facility's mammography Quality Assurance (QA) program meets all requirements. The administrative title and other supervisory responsibilities of the individual, if any, are left to the discretion of the VA medical facility.

j. **Screening Eligible Active Users.** Screening eligible active users are women Veterans greater than 40 years of age who are enrolled and receiving services at a VA facility within a 60-minute average drive time.

k. **Screening Mammogram.** A screening mammogram is a radiological breast examination in an asymptomatic Veteran.

7. REFERENCES

a. P.L. 98-160, 102-539, 104-262, 105-114, 105-248, 117-135.

b. 38 U.S.C. § 7319.

c. 42 U.S.C. §§ 263b, 354.

d. 21 C.F.R. Part 900.

e. VHA Directive 1043, Restructuring of VHA Clinical Programs, dated November 11, 2016.

f. VHA Directive 1088, Communicating Test Results to Providers and Patients, dated July 11, 2023.

g. VHA Directive 1104, Radiology Picture Archiving and Communication Systems (PACS), dated September 1, 2017.

h. VHA Directive 1330.01(7), Health Care Services for Women Veterans, dated February 15, 2017.

i. National Center for Health Promotion and Disease Prevention (NCP), https://vaww.prevention.va.gov/CPS/Screening_for_Breast_Cancer.asp. ***NOTE:*** *This is an internal VA website that is not available to the public.*

j. ACR Accreditation Application Process for FDA-Approved Digital Breast Tomosynthesis (DBT) Systems: https://www.fda.gov/radiation-emitting-products/facility-certification-and-inspection-mqsa/digital-breast-tomosynthesis-dbt-system.

k. ACR BI-RADS Atlas®, Breast Imaging Reporting and Data System (most current edition): https://www.acr.org/Clinical-Resources/Reporting-and-Data-Systems/Bi-Rads.

l. ACR Digital Mammography, Quality Control Manual (most current edition): https://www.acraccreditation.org/resources/digital-mammography-qc-manual-resources.

m. ACR, Mammography Accreditation: http://www.acraccreditation.org/Modalities/Mammography.

n. ACR Practice Parameter for Communication of Diagnostic Imaging Findings: https://www.acr.org/-/media/ACR/Files/Practice-Parameters/communicationdiag.pdf?la=en.

o. ACR Practice Parameter for the Performance of Contrast-Enhanced MRI of the Breast: https://www.acr.org/-/media/ACR/Files/Practice-Parameters/MR-Guided-Breast.pdf.

p. ACR Practice Parameter for the Performance of Screening and Diagnostic Mammography: https://www.acr.org/-/media/ACR/Files/Practice-Parameters/screen-diag-mammo.pdf?la=en.

q. FDA, Radiation–Emitting Products, Mammography Quality Standards Act and Program: https://www.fda.gov/radiation-emitting-products.