

MAMMOGRAPHY PROGRAM PROCEDURES AND STANDARDS

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) directive is issued to provide policy for the administration, accreditation, staffing, and functioning of mammography programs in Department of Veterans Affairs (VA) facilities, facilities managed by VHA, and community-based outpatient clinics (CBOCs) or leased facilities.

2. SUMMARY OF MAJOR CHANGES: This revised VHA directive updates implementation instructions and procedures for the administration, accreditation, staffing, and performance of mammography programs in VA facilities; those managed by VHA, CBOCs, and leased facilities. Changes include:

- a. Incorporating VHA Handbook 1105.03, dated April 28, 2011.
- b. Adoption of American Cancer Society breast cancer screening guidelines.
- c. A requirement that facilities complete implementation of this directive no later than July 16, 2018.

3. RELATED ISSUES: VHA Directive 1330.01, Health Care Services for Women Veterans; dated February 15, 2017, and VHA Directive 1088, Communicating Test Results to Providers and Patients, dated October 7, 2015.

4. RESPONSIBLE OFFICE: The National Director, Radiology Program, Diagnostic Services (10P11D), is responsible for the contents of this directive. Questions may be referred to (919) 384-8593.

5. RESCISSIONS: VHA Handbook 1105.03, Mammography Program Procedures and Standards, dated April 28, 2011, is rescinded.

6. RECERTIFICATION: This VHA directive is scheduled for recertification on, or before the last working day of May 2023. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

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

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MAMMOGRAPHY PROGRAM PROCEDURES AND STANDARDS

1. PURPOSE

This Veterans Health Administration (VHA) directive establishes policy for the performance and interpretation of Radiologic Mammography services in Department of Veterans Affairs (VA); medical facilities as required by Federal statutes and regulations. It also provides procedures for the administrative structure and management of mammography services provided in VHA medical facilities and their outreach functions. This directive further defines requirements unique to VHA. Unless otherwise stated, requirements found in this directive are specifically intended for use and application for VHA in-house, on-site mammography programs that provide breast imaging services to women, men, and transgender Veterans. **AUTHORITY:** Title 38 U.S.C. 7319, 7322

2. BACKGROUND

VHA has been providing routine mammography to Veterans since the passage of Public Law 98-160, the Veterans' Health Care Amendments of 1983. VHA mammography programs may range in complexity and configuration from a comprehensive on-site program that provides screening, diagnostic mammography, and interventional procedures to on-site programs that provide limited services. VHA medical facilities with a small number of active women enrollees in VA healthcare provide mammography services through community care providers.

3. DEFINITIONS

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

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

c. **Full Field Digital Mammography.** A 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.

d. **Diagnostic mammography.** A diagnostic mammogram is ordered for patients that have clinical signs or symptoms of breast disease, or if the radiologist detected findings of concern on a screening mammogram and ordered additional mammographic views.

e. **Digital Breast Tomosynthesis.** A 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. Tomosynthesis can reduce or eliminate the tissue overlap effect.

f. **Interpreting Physician.** An interpreting physician (IP) is a physician who is qualified to independently interpret mammograms by meeting MQSA requirements.

g. **Lay Summary Report.** A summary of the written report that is sent directly to the patient in terms easily understood by a lay (non-medical) person.

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

i. **Lossless Compression.** Data compression techniques in which no data is lost.

j. **Lossy Compression.** Data compression techniques in which some data is lost and cannot be reversed.

k. **Mammography Program.** A mammography program refers to a specific VA Radiological subspecialty department operating on-site within the larger context of a VHA facility's physical plant.

l. **Ordering Practitioner.** An ordering practitioner is a practitioner authorized to enter and sign orders for diagnostic tests by privileges or acting under a scope of clinical practice.

m. **Other Qualified Personnel.** Other qualified personnel mean persons with documented technical training appropriate for the task(s) assigned to them. Examples include a radiological technologist qualified under MQSA with appropriate training, a technologist who is trained to do the QC test(s) by the Lead Mammography Quality Control (LMQC) Technologist or other radiology support persons appropriately trained to do the task(s) and supervised by the LMQC technologist. A receptionist, clerk, or a secretary whose sole qualification is to copy documents, type, make appointments or answer the phone is not included under "other qualified personnel."

n. **Screening mammogram.** A screening mammogram is a radiological breast examination in asymptomatic, average-risk women.

4. POLICY

All mammography performed within VA for the diagnosis or detection of breast cancer must meet the requirements of 21 CFR Part 900 (MQSA), be in compliance with the procedures outlined in this directive, meet the requirements of applicable VA and VHA policies and procedures listed in the references, and where relevant, must also meet other applicable requirements.

5. RESPONSIBILITIES

a. **Under Secretary for Health.** The Under Secretary for Health is responsible for ensuring overall VHA compliance with this directive.

b. **Office of the Principal Deputy Under Secretary for Health.** The Principal Deputy Under Secretary for Health is responsible for ensuring that VA retains exclusive oversight and enforcement responsibilities even though accreditation, mammography standards inspections, exam interpretation, procedure performance, and medical physicist responsibilities may be performed by independent third parties.

c. **Director, National Radiology Program.** The Director, National Radiology Program is responsible for:

(1) Ensuring all VHA mammography programs maintain current accreditation with the ACR and successfully obtain approval to provide mammographic services by receiving VHA certification.

(2) Recommending Denial, Revocation, Suspension, or Termination of Certification. The Director, National Radiology Program, recommends to the Principal Deputy Under Secretary for Health through recognized organizational channels, action to revoke, suspend, or terminate the certification of VHA mammography programs that do not comply with, or meet, established mammography standards as found in 21 CFR Part 900, or programs that have demonstrated ongoing and uncorrected deficiencies, or otherwise fail to meet VHA policy. VA medical facilities may appeal denial of certification directly with the Director, National Radiology Program. The Principal Deputy Under Secretary for Health may approve, remand, or reject recommendations by the National Director Radiology Program.

d. **Mammography Program Director.** The Mammography Program Director reports to the National Director, Radiology Program and is responsible for:

(1) Collecting and analyzing compliance data from all VHA on-site mammography programs. On a routine basis, mammography inspection and accreditation results are provided by VHA Mammography Program Office (VHAMO) to the individual facilities and National Director Radiology for use in program improvement, compliance, and oversight activities.

(2) Providing recommendations on interpretation of regulatory requirements found in Federal statutes, regulations, and guidance pertaining to mammography quality standards.

(3) Preparing recommendations to Veterans Integrated Service Networks (VISNs) on the baseline requirements for program establishment, continuation, or closure.

(4) Developing recommendations to the National Director, Radiology Program, concerning program certification; i.e., granting extension, revocation, suspension, or denial.

(5) Providing periodic on-site visits to ensure maintenance of corrective actions and compliance with the AB and FDA requirements consistent with 21 CFR Part 900.

e. **VA Medical Facility Director.** VA Medical Facility Directors are responsible for ensuring policies and procedures related to quality, patient education, effective and clear communication with patients, clear communication of mammography results, infection control, and safety are developed and implemented following the ACR practice guidelines and the ACR QC manual.

f. **Facility Chief of Staff.** VA Medical Facility Chiefs of Staff are responsible for ensuring that each facility has a process in place to ensure tracking and timely follow-up of findings from breast cancer screening.

g. **Chief, Radiology Service.** The Chief of Radiology Service is responsible for:

(1) Indirect Oversight. While the Chief Radiologist is not directly responsible for the content of the results released by the IP(s), the Chief Radiologist is ultimately responsible for the program's compliance with 21 CFR Part 900, and VHA policies which include compliance with VHA-imposed measures and monitors, critical results communication, credentialing, etc.

(2) Mammography QA Program. 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 to perform these duties. All monitors used in the interpretation of mammography and all printers used by the program must be FDA-approved, comply with a QA program that is substantially the same as that recommended by the FFDM manufacturer, and pass the ACR's phantom and clinical image review process.

(3) VHA Mammography Programs with VHA Interpreting Physician Staff.

(a) The Chief Radiologist designates a LIP who has the responsibility of ensuring that the QA program meets Federal requirements.

(b) The overall direction and coordination of the functions of the program based on the mission, special needs, and size of the facility may be delegated, as appropriate, to the LIP.

(c) The names of the LIP, medical physicist(s), QC technologist(s), Audit IP(s), and any other program personnel with delegated QA responsibilities must be placed in writing.

(d) The Chief Radiologist must issue a statement of responsibilities. Because the regulations, 21 CFR 900.12(a)(1)(30, 2(rr)), already specify the responsibilities of the LIP, medical physicist(s), QC technologist(s), and Audit IP(s), 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 LIP, medical physicist(s), QC technologist(s), or Audit IP(s), a statement of responsibilities and the credentials for that individual(s) must be provided.

(4) VHA mammography programs with Non-VHA IP Staff.

(a) For mammography programs which may employ a contractor, fee basis, or local contractor as the mammography IP, the Chief Radiologist must identify a LIP who has the general responsibility of ensuring that the contractor, fee basis, or locum tenens QA program meets all requirements.

(b) The Chief Radiologist must clearly and specifically include the following within the contract which must be managed in such a manner as to ensure compliance with 21 CFR Part 900.

(c) The names of the LIP, medical physicist(s), QC technologist(s), Audit IP(s) and any other program personnel with delegated QA responsibilities must be placed in writing.

(d) If the program delegates QA responsibilities to someone other than the LIP, medical physicist(s), QC technologist(s), or Audit IP(s), a statement of responsibilities for that individual(s) and their credentials must be provided.

h. **Lead Interpreting Physician (LIP)**. The LIP is a mammography qualified IP and is responsible for:

(1) Ensuring the QA program, including personnel assignments, all equipment quality control tests, records, corrective actions, the annual physicist's survey, and medical audit and outcome analysis meet the required standards in 21 CFR Part 900.

(2) Ensuring the individuals assigned to QA tasks are qualified to perform these tasks and that their performance is adequate. **NOTE:** *Non-VHA LIPs are expected to make recommendations to the Chief Radiologist.*

(3) Reviewing and discussing medical outcome audits with the IP or assigning this task to another IP (as the Audit IP). The responsibilities of the Audit IP, who must also be a qualified IP, must be consistent with 21 CFR 900.12(f)(3). For programs with only one IP, that person will be the LIP.

(4) Participating in the 3 year accreditation renewal process, the annual FDA inspection, and any other review of mammography quality within the program or required by 21 CFR 900.12 (d)(1)).

(5) Designating a LMQC technologist who meets the mammography technologist requirements, and who is responsible for those QA responsibilities not assigned to the LIP or to the medical physicist. **NOTE:** *Non-VHA LIPs also make recommendations for designation to the Chief Radiologist.*

(6) Being directly involved in the selection of a qualified medical physicist to, at a minimum, annually survey the mammography equipment. Because the duties of the medical physicist encompass more than just the annual physics survey, it is an expectation that program staff are able to call on the services of the qualified medical physicist throughout the year, as needed, to maintain the mammography system.

NOTE: *Non-VHA LIPs are expected to make recommendations to the Chief Radiologist.*

i. **Audit Interpreting Physician (AP)**. The AP is responsible for conducting and reviewing the medical outcomes audit data.

j. **Interpreting Physician (IP)**. The IP is responsible for:

(1) Consulting with referring clinicians regarding the medical significance of the clinical images.

(2) Ensuring the quality of mammography images, they interpret and the content of the reports they verify. IPs need to provide frequent and consistent feedback to the LIP and mammography technologists, according to facility and service policies, concerning the images they are asked to interpret.

(a) High-quality images and QC practices need to be recognized, reinforced, and rewarded.

(b) Poor-quality images need to be identified and improved, as image quality affects the detection of potential breast cancers and abnormal breast conditions, and affects treatment planning.

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

(4) Providing feedback on image quality and QC practices to the LIP and Chief Radiologist, and participating in the facility's mammography medical outcomes audit program.

NOTE: *Non-VHA IPs are responsible for providing feedback on VHA IP performance to the Chief Radiologist.*

(5) Communicating results to patients according to 21 CFR part 900 and to ordering providers.

k. **Medical Physicist**. The Medical Physicist must:

(1) Be qualified to survey mammography equipment and oversee the equipment-related QA practices of the program.

(2) Ensure the program's annual survey includes all the annual quality control tests specified in 21 CFR 900.12(e)(8)(ii)(B), the phantom image quality test, the other (including new) mammographic modality tests, as well as an evaluation of the quality control tests and results that are normally conducted by the QC technologist,

(3) Provide the program with a report of the annual survey.

(4) Ensure mammography equipment evaluations are done (when applicable), e.g., after equipment moves, major equipment repairs, and for new equipment placed into service, as set forth in 21 CFR 900.12(e).

(5) Non-VA physicists are required to comply with the same requirements in reference to mammography as a VA physicist.

I. **Lead Mammography Quality Control (LMQC) Technologist.** The LMQC Technologist is responsible for:

(1) Ensuring all individual tasks within the QA program not assigned to the LIP or to the Medical Physicist are assigned to a qualified LMQC technologist. **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 personnel 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 the regulations. **NOTE:** *FDA recommends having a single LMQC technologist. FDA has found this is a best practice with less fragmentation and generally allows for better management of the mammography program with more consistent results.*

(2) Apprising program staff of new mammography standards and modifications to existing mammography standards and of guidance authored by VHA, FDA, ACR, and acting as a resource to the LIP.

(3) Ensuring the program has available current copies of pertinent VHA policies, standard operating procedures (SOPs), and guidance documents dealing with mammography to include inspection, accreditation requirements, equipment QC, and the proficiency programs.

(4) Ensuring all assigned QC and QA tasks are performed in a professional, trackable, and verifiable manner.

(5) Being the point of contact for the FDA mammography standards inspections in the absence of, or as a designee of, the Chief Radiologist or LIP.

(6) Analyzing inspection reports of the program to identify problems and trends, and reporting this information to appropriate facility management and to the Chief Radiologist.

(7) 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.

(8) Reviewing investigation reports from the FDA, ACR, Office of the Inspector General (OIG), and Medical Inspector (MI) dealing with the mammography program, and following up with the Chief Radiologist and with the LIP to ensure that issues identified in these reports are addressed timely and, as specified in the reports, corrected.

(9) Advising the Chief Radiologist and the LIP of problems and concerns affecting the quality of the work in the program.

(10) Working with the VHAMO to ensure that the program is in compliance with the inspection and accreditation requirements set forth by ACR, FDA, and VHA policies.

NOTE: VHA's Breast cancer screening guidelines can be found on the National Center for Health Promotion and Disease Prevention website:

http://vaww.prevention.va.gov/CPS/Screening_for_Breast_Cancer.asp. **NOTE:** This is an internal VA Web site that is not available to the public.

(11) Reviewing records (see Appendix C).

m. **Mammography Radiologic Technologist.** The Mammography Radiologic Technologist's responsibilities center on patient care and image quality. More specifically, these include:

- (1) Patient positioning;
- (2) Compression;
- (3) Image acquisition; and
- (4) Infection control.

6. REFERENCES

- a. Public Law 98-160 Veterans' Health Care Amendments of 1983
- b. Public Law 102-539 Mammography Quality Standards Act (MQSA) of 1992
- c. Public Law 104-262 Veterans' Health Care Eligibility Reform Act of 1996
- d. Public Law 105-114, Section 208 Veterans' Benefits Act
- e. Public Law 105-248 Mammography Quality Standards Re-Authorization Act of 1998
- f. 38 U.S.C. 7319
- g. 42 U.S.C. 263b, 354
- h. Title 21 Code of Federal Regulations (CFR) Part 900, Mammography
- i. VHA Directive 1088, Communicating Test Results to Providers and Patients, dated October 7, 2015
- j. VHA Directive 1330.01, Health Care Services for Women Veterans, dated February 15, 2017

- k. VHA Handbook 1004.01, Informed Consent for Clinical Treatments and Procedures, dated August 14, 2009
- l. VHA Handbook 1120.05, Coordination and Development of Clinical Preventive Services Guidance, dated July 29, 2015
- m. ACR BI-RADS Atlas®, Breast Imaging Reporting and Data System (most current edition)
- n. ACR Practice Parameter for Communication of Diagnostic Imaging Findings
- o. ACR Practice Parameter for the Performance of Screening and Diagnostic Mammography.
- p. ACR Practice Parameter for the Performance of Contrast-Enhanced Magnetic Resonance Imaging (MRI) of the Breast.
- q. VHA Clinical Preventive Services Guidance Statement: Screening for Breast Cancer: http://vaww.prevention.va.gov/CPS/Screening_for_Breast_Cancer.asp.
NOTE: *This is an internal VA Web site that is not available to the public.*
- r. ACR Practice Parameter for the Performance of Stereotactic-Guided Breast Interventional Procedures.
- s. American Cancer Society, <https://www.cancer.org/health-care-professionals/american-cancer-society-prevention-early-detection-guidelines/breast-cancer-screening-guidelines.html>
- t. American College of Radiology, Mammography Accreditation: <http://www.acraccreditation.org/Modalities/Mammography>.
- u. Food and Drug Administration, Radiation–Emitting Products, Mammography Quality Standards Act and Program: <http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/default.htm>.

ACCREDITATION, CERTIFICATION AND ALTERNATIVE STANDARDS

This section addresses mammography accreditation, certification, and alternative standards for VA medical facilities interested in establishing or maintaining a mammography program.

1. ACCREDITATION

a. VA medical facilities must be accredited by an approved private non-profit organization which meets the requirements established under subsection (e) of Section 354 of the Public Health Service Act (42 U.S.C. 263b) to perform mammography. VA medical facility programs must exclusively use the American College of Radiology (ACR) for the Accreditation Body (AB), as the ACR is currently the only non-profit mammography accrediting body approved by FDA.

b. A VA medical facility interested in establishing a program and performing mammography on site must apply for and attain accreditation. Accreditation provides VA medical facilities with peer review and constructive feedback on staff qualifications, equipment, quality control, quality assurance, image quality, and radiation dose. All VHA mammography programs are required to register with the National Radiology Program's Mammography Program Office and be issued a VHA certification number.

c. All VHA mammography programs must be accredited by the ACR prior to any patient imaging. A program must be accredited before it can be certified by VHA. For new programs, provisional ACR accreditation must be attained and VHA Mammography Program Office (VHAMO) issue a provisional certification to perform mammography. ACR accreditation and VHA certification must be maintained to provide mammography services.

d. Programs need to allow 6 – 8 months for the reaccreditation process, which occurs triennially. A program has 45 calendar days from the date the testing materials are sent to the program to return the completed application and testing materials to the ACR. It is a local decision whether a site submits images to the ACR electronically or on film.

e. The clinical images submitted to the ACR are to be selected from those that are obtained from regularly scheduled female patients, while routinely performing screening mammograms. Legally, ethically, and morally it is an unacceptable practice to expose any patient repeatedly to obtain images for the clinical image review.

f. The ACR can, and is expected to take action to revoke or suspend the accreditation of facilities that do not comply with or meet established accreditation standards. Facilities may appeal denial of accreditation directly with the AB (see Appendix J).

g. Costs associated with the application for mammography accreditation activities, medical physicist surveys, and Additional Mammography Review(s) (AMR), if any, must be paid by the respective VA medical facility mammography program.

h. Costs and fees associated with the retention of qualified contract or fee for service medical physicist services as required by Federal regulations are the responsibility of the respective VA medical facility mammography program.

2. CERTIFICATION

a. Each independent VHA mammography program must be certified by VHA and issued a VHA certification number.

b. VHA mammography programs are required to revalidate their certificate with the VHA's Mammography Program Office after every successful 3-year accreditation renewal. A mammogram may not be legally performed at any VHA facility, unless the mammography program is both accredited and certified. **NOTE:** VHA may choose not to certify a program even after it has successfully been accredited to perform mammography. The decision not to award certification would be based upon internal VHA information and the concurrence of the Office of the Principal Deputy Under Secretary for Health.

c. VA mammography programs implementing digital breast tomosynthesis (DBT) must follow FDA's MQSA facility certificate extension requirements process. FDA will notify VHA to extend a site's mammography certificate to include DBT imaging. VA mammography programs may not use DBT imaging on patients until the VHAMO has extended their mammography certificate.

d. Costs associated with the FDA annual mammography standards inspections are centrally funded through a national Inter-Agency Agreement (IAA) between VHA and FDA. Costs of any additional or repeat program inspections by FDA due to inspection violations, etc., must be paid by the VA medical facility mammography program.

3. ADDITIONAL MAMMOGRAPHY REVIEW (AMR)

If VHA, or the AB, believes that mammography quality at a program has been compromised or may present a risk to human health, the program must provide clinical images and other relevant information, as specified, for review by the AB or to another entity designated by Office of the Principal Deputy Under Secretary for Health.

a. This additional mammography review assists the agency to determine whether the program is in compliance with 21 CFR Part 900, and if not, whether there is a need to make program modifications and notifications.

b. VHA may require notification of patients who received mammograms at the program and their referring physicians, of: the deficiencies presenting such risk, the potential harm resulting from the deficiencies, appropriate remedial measures, and such other relevant information as VHA may require. The notification must occur within a

timeframe and in a manner specified by the Office of the Principal Deputy Under Secretary for Health. VHA may require a program found to have performed mammography of compromised quality or that presents a risk to patients' health to notify the patients and their referring physicians of the deficiencies and of the risk or potential harm resulting from the deficiencies, of medical measures appropriate to the risk, remedial measures, and of any other relevant information VHA requires the facility to include in the notice.

4. ALTERNATIVE STANDARDS

a. An alternative standard is a means to ensure quality mammography replaces or augments existing regulatory standards. Alternative standards must be as effective in ensuring quality mammography as the standard it proposes to replace, and it must be in keeping with the purposes of 38 U.S.C. 7319 and 42 U.S.C. 263b. Alternative standards approved by FDA are acceptable for use by VA medical facilities, unless otherwise precluded by VHA policy.

b. VA medical facilities that would like to propose an alternative standard will need to develop the proposed standard following the guidelines found in 21 CFR 900.18 and submit it to the National Radiology Program, VHAMO, Suite 100, 3022 Croasdaile Dr., Durham, NC 27705, for review and assessment.

c. When a request is received, it is reviewed by the National Mammography Advisory Committee. Proposals with merit are referred to FDA for further comment prior to approval or implementation.

d. The National Director, Radiology Program, through the Chief Consultant, Diagnostic Services, or designee, may recommend approval or denial, in whole or in part, of a request for an alternative standard. The requestor is notified if the proposal is denied and the reason for denial. If the request is approved, the written notice includes the effective date of the approval, a summary of the limitations and conditions attached to the approval, and any other information that may be relevant to the approved request.

FOOD AND DRUG ADMINISTRATION (FDA) MAMMOGRAPHY QUALITY STANDARDS ACT INSPECTIONS

VHA has entered into an InterAgency Agreement (IAA) with FDA to utilize Federal inspectors to conduct the mandatory annual mammography standards inspections and in so doing meet the requirements of 38 U.S.C. 7319 and 42 U.S.C. 263b. Mammography inspection results are reported to the individual program to provide feedback and to VHA for program analysis, oversight, and enforcement.

1. MAMMOGRAPHY QUALITY STANDARDS ACT INSPECTION COVERS THE FOLLOWING

- a. Equipment performance (including image quality (phantom) and radiation dose measurements);
- b. Technologist and physicist QC and QA tests, tasks, and records;
- c. Medical audit and outcome analysis records;
- d. Medical records, mammography reports, and clinical image quality; and
- e. Personnel qualification records.

2. INSPECTION REPORT SUMMARY

At the conclusion of the inspection, a summary report (results notification) is usually left with the program; it includes any variances or deviations from the standards. Non-compliances are categorized into four levels.

a. Level 1(L1) or Level 1 Repeat are the most serious. It indicates a failure to meet key requirements that may compromise the quality of mammography services performed by the program. 'Repeat' is a term used to identify identical violations found during two consecutive inspections and is considered to be of even greater severity.

b. In the absence of Level 1 non-compliances, a Level 2 (L2) or Level 2-Repeat non-compliance indicates that the program meets all key requirements, but fails to meet significant mammography quality items.

c. In the absence of L1 and L2 non-compliances, Level 3 non-compliances indicate that the program meets all major requirements with minor exceptions.

d. The program meets national mammography standards as denoted by FDA as being in Full Compliance or no non-compliances. No action is required.

e. Each mammography program LIP with L1 or L2 non-compliance must prepare a written response, through their respective VA medical facility Director to VHAMO, outlining the program's corrective action plan to resolve the violation(s).

f. VHAMO, after receipt of the official report from FDA, sets a facility response date to be determined by the severity and number of violations. While the program is expected to correct each violation found during the inspection as soon as possible regardless of its level, it is generally not required to send a written response concerning L3 violations.

g. Corrective actions regarding all violations, no matter the level, are checked during the next annual inspection to ensure resolution.

3. CORRECTIVE ACTION PLAN

a. A corrective action plan consists of:

(1) A written narrative describing the findings of the program's investigation of the violations, including the conclusions as to the cause(s) of each unacceptable result;

(2) Specific actions taken to prevent reoccurrence; and

(3) Evidence that the problem has been corrected.

b. The number of violations, the severity level, context of the violations, and inspector remarks, may also indicate that additional steps need to be taken. The National Director of Radiology, using established channels, recommends appropriate action through the Principal Deputy Under Secretary for Health, who may require the program and facility to take additional actions, such as:

(1) Providing additional documentation;

(2) Ensuring additional staff training, as deemed appropriate, to resolve the violations;

(3) Implementing further corrective action;

(4) Removing equipment from use;

(5) Re-reading mammograms;

(6) Recalling patients improperly exposed;

(7) Suspending the performance of mammography; or

(8) Closing the program.

c. Mammography may continue to be performed while corrective action is being reviewed and implemented, unless otherwise directed by the office of the Principal Deputy Under Secretary for Health. If the program must cease, temporarily or permanently, while the program undergoes further assessment, e.g., Additional Mammography Review (AMR) or site visit, resumption of mammography may only be

authorized once the program and facility management can verify to the Principal Deputy Under Secretary for Health that the following conditions have been met:

(1) There is no immediate jeopardy to patient health and safety.

(2) The program has provided the Principal Deputy Under Secretary for Health with satisfactory evidence that it has taken steps to correct the problem(s) identified by the unsuccessful performance.

(3) The VA medical facility mammography program, as part of their QA activities, documents periodic, not less than quarterly, reassessment of the corrective action(s) implemented to ensure continued compliance and to prevent violation reoccurrence.

NOTE: *The VHAMO may request submission of evidence of the quarterly reviews to verify actions and progress.*

4. INSPECTION APPEAL PROCEDURES

a. The National Director of the Radiology Program is responsible for overseeing performance by and follow-up with the individual programs to ensure any needed corrective action(s) have been taken to remedy deficiencies. **NOTE:** *FDA is a contractor for VHA performing a nationally-mandated inspection service and provides VHA with the results of the inspections. VHA retains program oversight and enforcement responsibilities.*

b. It is important to document, with photo copies (if pertinent), the items and issues the inspector cited.

c. Any correspondence including an appeal must be submitted through appropriate VA medical center channels and is to include:

(1) A copy of the inspection non-compliances and results report;

(2) A clear statement of the non-compliance issue(s);

(3) Reference(s) to any mammography standards, final mammography regulations, or excerpts from guidance documents that support the program's position. Include copies of supporting documentation, such as a statement of whether the necessary documentation was made available for the inspector's review at the time of the inspection, or the date it was provided to the FDA inspector.

(4) The memo and accompanying documents are to be sent to VHAMO. Once it is reviewed, the materials may be forwarded to FDA for review and comment. The program receives a reply in writing from VHAMO, affirming or reversing the cited findings of non-compliance(s). VHA apprises FDA of the final outcome of the review.

MAMMOGRAPHY PROGRAM DOCUMENTS MANAGEMENT

1. RECORD KEEPING

A system for generation, retention, storage, and retrieval of all required mammography records must be maintained; this is to ensure that:

a. Records are completed according to instructions in the relevant SOPs or policies, which are derived from public law, Federal regulations, and VA policies.

b. Records are stored in a manner which maintains their integrity and which permits their retrieval within a reasonable time-frame as defined by the most stringent requirements of VA, FDA, or the accrediting body (see VA Records Control Schedule (RCS) 10-1).

c. Records are retained for the required period(s) as defined by the most stringent requirements of VA, FDA, or the accrediting body (see RCS 10-1).

2. STANDARD OPERATING PROCEDURE (SOP) DOCUMENTS

a. A comprehensive SOP manual, developed by each mammography program, covering critical functions (technical, clerical, and administrative) performed by the program must be maintained.

b. The SOP documents must be current and must reflect the actual practices in the program.

c. Operator's manuals, manufacturer's package inserts, or textbook procedures may be used as a supplement to, or referenced by, the SOP. A copy of any literature referenced by the SOP must be physically present for review.

d. The SOP must be readily available to all mammography program staff.

e. Any deviation from SOP, and justification for such deviation, must be approved and documented by the LIP.

MEDICAL PHYSICS SURVEYS

a. Every 12 months, but not more than 14 months from the previous survey, each mammography program must be surveyed by a mammography qualified medical physicist, or by someone in training under the qualified medical physicist's direct supervision. The survey must comply with the requirements of 21 CFR 900.12(e) and be available to the program employee requesting the survey, Chief Radiologist, the LIP, and the mammography QC technologist within 30 days of the date of the survey.

b. The annual tests which are part of the survey must be performed using technical factors and test conditions as stated in the regulations, whenever those factors are specified. Otherwise, technical factors that are clinically used in the program must be utilized.

c. Problems with test performance, survey conduct, report content, and the like must be directed to the qualified medical physicist or Contracting Office, if contract medical physicist services are used.

QUALITY ASSURANCE, QUALITY CONTROL, AND QUALITY ADMINISTRATION PROGRAM

This appendix addresses quality assurance (QA), quality control (QC) activities, and the Quality Administration Program. Quality assurance activities can be subdivided into two major categories: QC procedures and Quality Administration procedures. The radiologist, medical physicist, and QC technologist, working together as a team, are the keys to providing optimum quality mammography images, which will ultimately provide the best medical care possible to the patient.

1. QUALITY ASSURANCE

a. QA in mammography is defined as those planned and systematic activities that monitor and improve the early detection of breast cancer and the evaluation of breast disease.

b. QA program content must meet VHA requirements; Performance Standards for Ionizing Radiation Emitting Products (21 CFR 1020.30, and 1020.31); Occupational Safety and Health Administration (OSHA)'s Blood Borne Pathogens Standard (29 CFR 1910.1030); and the national mammography requirements found in 21 CFR Part 900.

c. QA activities include the employment, training, continuing education, and continuing experience of qualified personnel.

2. QUALITY CONTROL PROCEDURES

a. QC includes the technical components of QA: equipment selection, equipment performance evaluation and routine equipment monitoring, technique factor selection, and evaluation of breast positioning and compression.

b. Performance of required QC tests must include clear and legible documentation. The documentation must include test results and the dates when the tests were performed. For each test result that falls outside the action limits, the documentation must also include the date and the corrective actions taken and the results. Data results need to be properly charted or tabulated. **NOTE:** *VA medical facilities may consult any appropriate QC manual for examples of charts and tables or establish their own format for documenting the test data and results, as long as they are consistent with the final regulations. Special attention needs to be given to the AB guidance manuals, manufacturers' QC manual recommendations, and other approved documents concerning testing methodologies.*

c. Documentation must be maintained between inspections. QC documentation must be securely retained for a minimum of two successive FDA annual inspections. However, if QC records for a given test were found to be deficient and the program was cited during an annual inspection, these records must be kept until the all deficiencies are corrected and the records have been subsequently reviewed by the FDA inspector during three successive annual inspections.

3. QUALITY ADMINISTRATION PROGRAM

a. Quality administration includes monitoring methods that assess interactions and communications between the mammography provider and the patient, and between the IP and the referring physician. It includes steps that assess the skills of the IP by comparing screening and diagnostic results with patient outcomes and other administrative monitors of clinical quality, such as: the evaluation of patient-staff interactions, reporting of abnormal results, report content, dictation timeliness, efforts to improve patient care tracking, and follow-up.

b. Infection Control and Program Cleanliness. All VHA mammography programs are required to have an Infection Control and Program Cleanliness policy and log.

(1) Comply with current VHA directives and other applicable standards related to infection control.

(2) Maintain the proper engineering controls, work practices, and the use of manufacturer recommended biological products in order to reduce the potential for spread of infectious microorganisms to patients, visitors and VA employees.

(3) Establish and follow a protocol for cleaning and disinfecting mammography equipment that has come in contact with blood, other body fluids, or potentially infectious materials consistent with 21 CFR 900.12(e)(13). **NOTE:** *Additional guidance can be found in OSHA's Bloodborne Pathogens Standard (29 CFR 1910.1030), obtained from facility infectious disease staff, and the mammography equipment manufacturer's specified disinfection procedures.*

(4) Have written documentation that shows the steps the program takes for cleaning and disinfecting mammography equipment after contact with blood and other potentially infectious materials. If reference material is cited in the program's description of its procedures, such as manufacturer's requirements, the program must have a copy of the referenced material available.

(5) Have documentation (e.g., logs or charts) that indicate the infection control procedures were performed when the mammography equipment came into contact with blood or other potentially infectious materials; this documentation must be kept and available for posting and review. In those cases, where there has not been an episode of contamination, the documentation is to clearly show that fact for FDA inspector reference.

c. Image Viewing Considerations.

(1) Mammography programs, where screen-film mammograms are interpreted or reviewed for comparison must establish, document, and follow adequate protocols for darkroom, screen and viewbox cleanliness, and viewing conditions consistent with 21 CFR 900.12(e)(11). **NOTE:** *Examples of protocols may be found in documents by the AB, in FDA guidance, and specific recommendations by the equipment manufacturer.*

Acceptable documentation would be written procedures for performing the corresponding cleaning activities with records showing that each was conducted at the designated frequency, and was followed, when needed, by the appropriate corrective actions.

(2) The program must provide both hot lights and masking devices to the IPs. Any device that blocks light not required for viewing and interpretation of the image must meet the masking requirement. **NOTE:** *Although not specifically required, it is recommended that hot lights and masking devices be available for technologists to aid in their evaluation of clinical and quality control films.*

(3) If a separate view box is used by the LMQC technologist to check the optical density and quality of the mammography films, this viewbox needs to be similar to the reading viewbox in luminance and color of the light; in addition, it needs to be used with ambient lighting conditions similar to those in the room where the mammograms are interpreted.

d. Digital Monitors and Display Stations.

(1) Only digital monitors and display stations specifically approved or cleared for full field digital mammography (FFDM) use by FDA's Office of Device Evaluation are used by VHA programs in the interpretation of mammograms. Monitors used by the program with its FFDM system need to ensure compliance with a QA program that is substantially the same as that recommended by the FFDM manufacturer. **NOTE:** *VA medical facilities have the option to submit images electronically to the ACR.*

(2) Each digital and hardcopy mammographic films used for final interpretation must be labeled as required by 21 CFR 900.12(c)(5). Each image must have a permanent ID label containing at least: the VA medical facility name, city, state, and ZIP code; the patient's first and last name; and an additional patient identifier; the date of the examination; view and laterality placed on the image near the axilla; technologist identification; cassette identification (CR only); and mammography unit identification.

e. Medical Outcomes Audit

(1) A comprehensive mammography quality assessment program evaluates equipment, image quality, and image processing, and also evaluates the appropriateness and accuracy of image interpretation. Aggregate medical outcome audit data provide a picture of how the program is detecting breast cancer among its patients. Individual analyses are important to identify IPs whose outcomes are very different from the aggregate. The intent of mammography medical audit outcomes tracking is for IP quality improvement. It is not to ensure the patient's ordering practitioner is addressing continuing follow-up and treatment based on the communicated results.

(2) Each mammography program must have established a system, consistent with 21 CFR 900.12(f), to collect and review mammogram interpretation outcome data, to track positive mammograms, and to correlate the findings with biopsy results.

(3) The mammography medical audit system must be able to document the identification of the Audit IP(s).

(a) A definition of “positive mammograms” requiring follow-up. **NOTE:** *Positive mammograms are defined by FDA as those with a final assessment category of “Suspicious” or “Highly Suggestive of Malignancy.”*

(b) A method established by the mammography site to follow-up mammograms identified as ‘positive’ with the auditing IP.

(c) Attempts to collect pathology results for all breast biopsies performed. Collection of additional information is suggested, such as staging and size of tumors, as these data enhance evaluation of success in early detection of breast cancer.

(d) Methods to correlate pathology results with the final assessment category indicated by the IPs. **NOTE:** *Beyond the requirement that each mammography program must have a system for collecting outcome information, FDA has not established specific requirements for statistical data collection. Mammography programs can refer to radiology journals, broader medical literature, and the latest ACR BI-RADS Breast Image Reporting and Data System Atlas for information regarding recommendations for the collection of data.*

(e) A method to include any cases of breast cancer among patients imaged at the program that subsequently become known must prompt the program to initiate follow-up on surgical and pathology results and a review of the mammograms taken prior to the diagnosis of a malignancy.

(f) A review of medical outcomes audit data for the aggregate of IPs, as well as each individual IP must be completed and documented for internal program use at least once every 12 months.

4. BREAST IMPLANTS

a. Each mammography program must meet the requirements of 21 CFR 900.12(g), to include a process to inquire whether or not the patient has breast implants prior to the actual mammographic exam; and

b. Except where contraindicated, or unless modified by a physician’s directions, patients with breast implants undergoing mammography must have mammographic views to maximize the visualization of breast tissue.

5. CONSUMER COMPLAINT PROCESS

a. To meet the requirements for addressing consumer complaints, mammography programs must provide written documentation that describes their system for recording, maintaining, and resolving patients' complaints. This documentation must include instructions to patients on how to refer serious unresolved complaints to the AB. The established procedures must meet the requirements of 21 CFR 900.12(h).

b. A serious complaint is an adverse event, which significantly compromises clinical outcomes, or an event for which a facility fails to take appropriate corrective action in a timely manner. Examples of adverse events include:

(1) Poor image quality;

(2) Missed cancers;

(3) The use of personnel who do not meet the applicable requirements of 21 CFR 900.12(a), and

(4) Failure to send mammography reports or lay summaries to the appropriate person(s) within 30 days.

c. The program is required to maintain a record of each serious complaint.

(1) If the program has received serious complaints, it must be able to produce records indicating that they are following their system and are maintaining the serious complaints for at least 3 years from the date the complaint was received.

(2) In addition, the program must provide the consumer with adequate directions for filing serious complaints with the AB if it is unable to resolve the complaint to the consumer's satisfaction. Unresolved serious complaints must be reported to the AB in a manner and timeframe specified by the AB.

(3) While not required, FDA encourages mammography programs to post a sign informing their patients of the presence of its complaint mechanism. Mammography programs can use messages such as, "We care about our patients. If you have comments, compliments, or concerns, please direct them to (the name of the person at the facility who is responsible for complaints)." Additional suggestions for making patients aware of the complaint mechanism include: providing information about the complaint mechanism on the patient information sheet filled out before the exam. FDA encourages the VA medical facility to train its staff, including non-VHA providers, to be receptive to patient concerns so that the patient will feel comfortable in expressing those concerns.

(4) A third party outside of the mammography program, e.g., the VA medical facility's patient representative or patient advocate, may handle complaints for the mammography program if it is part of the VA medical facility's written procedure for addressing complaints.

6. REPEAT ANALYSIS

a. The rationale for performing the repeat analysis is to evaluate reasons for repeated mammograms. The main reason for repeats usually comes from technologist performance; therefore, training or a change in behavior is recommended.

b. Under FFDM, the QA requirements focus on the manufacturer's QC manual. The manufacturers usually include repeat analysis as part of the unit QC testing so it also becomes a program requirement. The program is to have documentation that the repeat analysis is accomplished for FFDM systems consistent with 21 CFR 900.12(e)(3).

c. If the total repeat or reject rate changes from the previously-determined rate by more than 2.0 percent of the total images included in the analysis, the reason(s) for the change must be determined. Any corrective actions are to be recorded and results of the corrective actions must be assessed. Whether the analysis is performed after the program, or the individual technologist, has examined 250 mammogram patients is left up to the program, but in all circumstances, the analysis must be performed at least quarterly by the LMQC.

PATIENT REPORTS AND RECORDS MANAGEMENT

This section addresses in-house and outsourced mammography patient reports, additional mammographic and non-mammographic images, communication of results to the provider and patient, and records management.

1. PATIENT REPORTS

a. Inclusion in Veterans Information Systems and Technology Architecture (VistA). All mammography reports regardless of where the procedure(s) are performed, in house, by other certified VHA mammography programs, or by non-VA care at VA expense, must be entered into VistA. The appropriate National Diagnostic Code corresponding to the BI-RADS assessment category must also be entered (see Appendix H).

b. In-house Mammography Reports. Program procedures must be developed and documented for preparing a written report of the results of each mammography examination, consistent with 21 CFR 900.12(c). Reports must be entered into the VistA Radiology Package. FDA-approved language corresponding to the appropriate BI-RADS assessment category must be included in the Impression section of the report. The BI-RADS code must be entered as a Diagnostic Code into the primary diagnostic code field according to the table in Appendix H, allowing activation of Clinical Reminders and Alerts in the Computerized Patient Record System (CPRS). Use of breast density diagnostic codes found in Appendix I are not required under MQSA. If a program chooses to use them, the code should be entered into the secondary diagnostic code field.

c. Outsourced Mammography Reports. If the radiologist has access to VistA or uses the radiology service dictation system the radiologist may enter the reports in the VistA Radiology Package. If reports are received on paper, they must be scanned into VistA Imaging and linked to an administrative report in VistA/CPRS. Patient reports must be incorporated into VistA either by software modifications or by scanning a copy of the paper report into VistA Imaging and associating it with an order for an outside radiology procedure in CPRS. The administrative report is a placeholder that states words to the effect that “an outside paper mammography report has been scanned into VistA Imaging.” The BI-RADS code must be included in the administrative report. The Outside Report menu option of the Radiology Package can be used to facilitate this entry. The Diagnostic Code associated with the appropriate BI-RADS numeric code must be entered with the administrative report according to the table in Appendix H.

2. DICTATION TIMELINESS

Mammograms should be interpreted and the patient notified of their mammography results according to 21 CFR 900.12 regulations.

a. In-house Reports. Generally, screening mammograms should be interpreted within 48 hours of completion unless waiting for prior mammogram images. Diagnostic mammograms must be interpreted within 48 hours.

b. Outsourced Reports. Facilities should work with their Non-VA Care Office to ensure reports are received timely from community providers who supply imaging for Veterans at VHA expense.

3. REPORT CONTENT

a. There is no specific report format required, apart from the requirement that an overall assessment category be included within it (i.e., negative, benign). However, there are report guidelines endorsed and published by the ACR. One overall (final) assessment category for each mammographic examination is required, which must be consistent with 21 CFR 900.12(c). The final assessment category is to be based on the most suspicious lesion or finding. **NOTE:** *Individual assessments for other lesions, along with recommendations for their management, may also be included in the body of the report, but would not be included in a final assessment category.*

b. The mammography report content must include:

(1) The name of the patient and an additional patient identifier,

(2) Date of examination,

(3) The name of the IP who interpreted the mammogram, and

(4) One overall assessment category for the entire mammographic examination based on the most suspicious lesion or finding.

c. In cases where no final assessment category can be assigned due to incomplete work-up, "Incomplete: Need additional imaging evaluation" is to be assigned as an assessment and the reasons why no assessment can be made must be stated by the IP.

d. The IP must include recommendations to the ordering practitioner regarding any additional actions, which may need to be taken. All clinical questions raised by the ordering practitioner should be addressed in the report to the extent possible, even if the assessment is negative or benign.

4. FINAL ASSESSMENT REPORT CATEGORIES

FDA requires that a final assessment category be provided for each mammography report. FDA has chosen standardized wording for the categories in an attempt to achieve national uniformity. A Radiology Package software modification to allow in-house and outsourced mammogram report final assessment entry in VistA and linkage with the ACR's Breast Imaging Reporting and Data System (BI-RADS) codes must be utilized. **NOTE:** *ACR granted VHA permission to use the codes within the VHA*

system. FDA final assessment category wording must continue to be used. Final Assessment Category wording and the FDA acceptable word substitutions are found in Appendix H. Reporting only a BI-RADS numeric code alone does not meet the FDA requirements of providing an overall final assessment category.

5. ACR BI-RADS CODES

ACR BI-RADS Codes (and FDA standard nomenclature) are:

a. BI-RADS code 1 (Negative), indicates there is no mammographic evidence of malignancy.

b. BI-RADS code 2 (Benign), indicates there is no mammographic evidence of malignancy.

c. BI-RADS code 3 (Probably Benign) according to ACR, this is reserved for findings that are almost certainly benign, having less than a 2 percent risk of malignancy.

NOTE: *Published studies emphasize the need to conduct a complete diagnostic imaging evaluation before assigning a code 3 assessment; it is, therefore, inadvisable to render such an assessment when interpreting a screening examination. Short term follow-up is usually suggested.*

d. BI-RADS code 4 (Suspicious) and BI-RADS code 5 (Highly Suggestive of Malignancy), both of these codes are considered by FDA to be positive mammograms. As such, each program is required to track and trend this data in the (mammography) medical outcomes audit for IPs to be able to evaluate the appropriateness and accuracy of their image interpretation.

(1) BI-RADS code 4 (Suspicious) is reserved for findings that do not have the classic appearance of malignancy, but have a wide range of probability of malignancy that is greater than those in BI-RADS code 3. Thus, most recommendations of breast interventional procedures would be placed within this category. While further subdivision of BI-RADS code 4 is encouraged by ACR, it cannot be substituted for specific FDA Final Assessment Category wording.

(2) BI-RADS code 5 (Highly Suggestive of Malignancy) has a high probability (greater than or equal to (\geq) 95 percent) of being cancer. This category contains lesions for which one-stage surgical treatment could be considered without preliminary biopsy.

e. BI-RADS code 6 (Known Biopsy Proven Malignancy) is the code that is reserved for lesions identified on the imaging study with biopsy proof of malignancy prior to definitive therapy.

f. BI-RADS code 0 (Incomplete: Need Additional Imaging Evaluation) is the code which may be used to indicate that additional imaging is necessary or that prior comparison of films or images are needed to complete the interpretation.

(1) There are three general scenarios where BI-RADS code 0, 'Incomplete' may be used:

(a) The need to obtain additional mammographic images (e.g., magnification views) to complete the work up;

(b) To obtain non-mammographic images (e.g., breast MRI) to complete the work-up; or

(c) The need for prior mammograms for comparison purposes.

(2) The reasons why no assessment can be made in cases where no final assessment category can be assigned due to incomplete work-up must be stated in the report by the IP.

6. ADDITIONAL MAMMOGRAPHIC IMAGES

a. Same Day. Under Centers for Medicare and Medicaid Services (CMS) guidelines a program can claim separately screening and diagnostic exams done on the same patient on the same day. The report issued after additional mammographic imaging (e.g., spot, repeat, or magnification views) needs to reflect the final assessment category for the case following these additional procedures. The program has the option of issuing either separate or combined reports. If two reports are issued, each must contain its own overall final assessment. The program can report both exams on the "same piece of paper." A report of this nature must be communicated to the ordering practitioner and a lay summary to the patient, just as any other report would be communicated. If the program decides to issue a single combined report, it needs to be aware that:

(1) A single combined report must contain a single overall final assessment.

(2) The combined report must clearly state to the referring physician that it is combining the results of the screening and diagnostic studies. This is also important if questions ever arise about whether the exams were billed correctly.

(3) Issuing a single report with a single final assessment may skew the mammography program's medical audit results.

(4) Though some computerized reporting systems may consider this a single examination (rather than two), FDA still allows facilities to count both exams toward meeting the continuing experience requirement.

b. Patient Callbacks for Additional Imaging. If the patient must return for additional imaging, the original study may be initially resolved as BI-RADS 0 "Incomplete", the referring clinician informed of such and the patient, according to accepted protocol, scheduled for additional views. The mammography program performing additional views must issue a report reflecting the final assessment. The report must be

communicated to the referring practitioner and a lay summary communicated to the patient, just as any other report would be communicated.

7. ADDITIONAL NON-MAMMOGRAPHIC IMAGES

a. If non-mammographic imaging is recommended by the IP, the initial mammography report recorded as BI-RADS 0 would correctly stay as "Incomplete" and not require amendment or change.

b. According to FDA, if the assessment category is "Incomplete" (or BI-RADS 0) and the patient is referred for additional testing, such as ultrasound or MRI to complete the diagnosis, the mammography program does not have to revise the original report if, as a result of this referral, the (final) assessment is changed to some other category.

8. PRIOR IMAGE COMPARISON

The report issued following comparison with prior images must reflect the final assessment category for the case following the image comparison. A report of this nature must be communicated to the ordering practitioner and a lay summary communicated to the patient, just as any other report would be communicated.

a. Screening mammography is utilized for asymptomatic patients. Comparison images may be helpful to decrease the need for patient recall; however, prior comparison images may not always be available and are not always required to interpret the current mammogram.

b. Prior images are not received, the reason(s) why no assessment can be made and the recommendations to the ordering practitioner should detail the suggested workup (e.g., additional views or ultrasound).

9. REPORT ADDENDA

The report following comparison with prior images needs to reflect the final assessment category for the case.

a. The report must be communicated to the ordering practitioner, just as any other report would be communicated, and a lay summary provided to the patient, even if there is no change in the final assessment category or recommended course of action.

b. Where there is no significant change in the report, a simple statement that the comparison has been performed and that there is no overall change would satisfy the requirement.

c. If the addendum merely states that the mammographic findings have been discussed with the ordering practitioner, no additional lay summary is required.

10. COMMUNICATION OF RESULTS

a. All VHA and non-VA mammography programs are required to provide a report of the results of the mammographic examination to the patient and the ordering practitioner within 30 days, consistent with the requirements of 21 CFR Part 900.12(c). Furthermore, when the mammography report assessment is "Suspicious" or, "Highly Suggestive of Malignancy," (BI-RADS codes 4 or 5, respectively), the results and recommended course of action must be communicated as soon as possible.

b. It is the IP's responsibility to interpret the images and communicate results according to MQSA regulations to the patient; however, it remains the responsibility of the practitioner ordering the study to discuss the meaning of the findings with the patient and the alternatives for further study, treatment, or referral.

c. Communication to Patients. The written mammography report summary, in terms easily understood by a layperson, must be communicated to the patient within 30 days from the date of the procedure. This applies to every patient who receives a mammogram. An effective communication system must exist.

(1) If the assessment is "suspicious" or "highly suggestive of malignancy" the results and recommended course of action must be communicated as soon as possible. FDA guidance recommends the patient be notified of "Suspicious" or "Highly Suggestive of Malignancy" results within 3 to 5 days of interpretation. FDA's intent is to address patients' concerns about breakdowns in communication that prevent timely and appropriate diagnosis and treatment of breast disease. One way to achieve this is through direct verbal communication. However, prompt verbal communication with the patient does not obviate the need to also provide a written lay communication to the patient within 30 days of the date of the mammogram. Documentation of verbal communication in the patient's electronic medical record is required.

(2) Using the United States (U.S.) Postal Service to communicate results is fully acceptable and confirmation of receipt of the results is not required. The FDA requirement to communicate results to the patient can be fulfilled by mailing the lay summary to the patient (at the patient's last known address), even when the lay summary is returned to the program and marked as "undeliverable." The VA health care facility must pursue any other available options to contact the patient, to meet or exceed the local community standard of care, or comply with other VHA policy documents. This is especially true where the results are "Suspicious" or "Highly Suggestive of Malignancy."

(3) Computer-generated lay summaries are acceptable under the final regulations. The facility may develop appropriate procedures for providing these lay summaries to their patients. Secure email message through My HealtheVet is approved to communicate with patients. When electronic means cannot achieve protected communication, hard copy (paper) lay summaries must be provided.

d. Communication to Ordering Practitioners. The signed written report must be provided to the ordering practitioner within 30 days of the examination date.

(1) An effective communication system must exist; however, the details of such a system are left to the facility and need to be individualized to address the mammography program's specific situation. If using the U.S. Postal Service, confirmation of the receipt of these results is not required.

(2) If the assessment is "suspicious" or "highly suggestive of malignancy" the results and recommended course of action must be communicated to the ordering practitioner, or designee, as soon as possible. FDA guidance recommends the ordering practitioner be notified of "suspicious" or "highly suggestive of malignancy" results within 3 to 5 days of interpretation. The IP is to make reasonable attempts to ensure the ordering practitioner is promptly contacted with the mammography results, consistent with VHA policies for communication and documentation of abnormal results. If the ordering practitioner is not available, then reasonable efforts to contact a surrogate for the practitioner must be made and documented. Verbal communication with the ordering practitioner does not obviate the need to also provide a written report to the ordering practitioner within 30 days of the date of the mammogram. Documentation of verbal communication in the medical record is required.

11. ERROR IN A FINAL PATIENT REPORT

If an error is found on a final patient result, VHA policies and procedures to resolve the error(s) and effect appropriate correction and notification must be followed by the IP and the LMQC technologist. If the final assessment category and/or recommendations are changed, the patient and ordering practitioner must be notified.

12. RETENTION, RELEASE, AND LABELING

a. VHA Record Control Schedule (RCS) 10-1 item, 7200.11 contain the retention period of 10 year for any film maintained outside of VistA. If the image is digital and placed into CPRS including VistA Imaging, then the digital image takes on the record schedule of the Electronic Health Records, RCS 10-1, Item 6000.2

b. Generally, the Privacy Act regulations regulate release of mammograms and patient medical information. There are two sections of the record keeping requirement.

(1) For purposes of hardcopy film or digital image retention, the program must maintain, in retrievable form, either the hardcopy films or lossless full field digital data of final interpretation quality for the time periods specified in RCS 10-1.

(2) For purposes of transferring hardcopy films or digital images, the program must be able to provide the medical institution, physician, health care provider, patient, or patient's representative with final interpretation quality hardcopy film or lossless full-field digital images.

13. IMAGE IDENTIFICATION

Each digital and hardcopy mammographic films used for final interpretation must indicate identifying information, including patient name and an additional patient identifier, date of examination, view and laterality, facility name and location (at a minimum, the location shall include the city, state, and ZIP code of the facility), technologist identification, cassette/screen identification, and mammography unit identification which is consistent with 21 CFR 900.12(c)(5).

FULL FIELD DIGITAL MAMMOGRAPHY

Digital mammography offers many potential advantages over conventional screen-film techniques, particularly in processing, transmission, and image display. There are a variety of issues unique to digital imaging which need to be addressed under national mammography standards. VHA mammography programs must maintain, in retrievable form, either the original or lossless compressed full field digital data, or the hardcopy films of final interpretation quality for the time periods specified in RCS 10-1.

a. **Digital Mammography Equipment.** Only equipment specifically approved for Full Field Digital Mammography (FFDM) use by FDA's Office of Device Evaluation may be used in the interpretation and printing of digital mammographic images. Approved devices have an FDA-issued 510(K) number and an Indication For Use (IFU) statement, which includes mammography. The manufacturer must be able to provide both the 510(K) number and the IFU to confirm FDA approval.

(1) Physicist Evaluation. A physicist survey must be conducted by a qualified medical physicist at every 12 months, but not more than 14 months from the previous survey. A mammography equipment evaluation is needed on all new equipment, after each repair, and on a schedule in conformance with all regulatory requirements and accreditation standards. For example, whenever a new unit or film processor is installed, a unit or film processor is disassembled and reassembled at the same or a new location, or major components of a mammography unit or film processor are changed or repaired.

(a) VA medical facilities are responsible for ensuring the annual physicist surveys and mammography equipment evaluations are performed, completed, and any issues are corrected.

(b) Annual physicist survey and mammography equipment evaluation documentation must be retained according to MQSA regulations.

(2) Preventive Maintenance. Preventive maintenance is performed by the manufacturer service representative or a Bio-Medical engineer who has received training on the equipment, on a schedule which meets manufacturer recommendations and all applicable regulatory requirements and accreditation standards. Preventive maintenance documentation must be maintained, including equipment ID, preventive maintenance results, and corrective actions taken (i.e., equipment disposition).

(3) Quality Control (QC).

(a) QC is performed by the Medical Physicist or LMQC on each type of equipment based on manufacturer's recommendations or according to ACRs Digital Mammography QC manual, regulatory requirements, accreditation standards, and internal requirements. **NOTE:** *FDA has not approved the new ACR Digital Mammography QC Manual for digital mammography systems with advance applications. If a VA medical facility chooses to follow the ACR Digital Mammography*

Quality Control Manual for its QC program, it is no longer required to follow its manufacturer's QC manual when performing ACR-required calibration or troubleshooting tests.

(b) QC documentation is maintained by the LMQC, including equipment ID, QC results, actions taken, and equipment disposition.

(4) Defective Equipment. Any defective equipment must be temporarily removed from service and evaluated either by Bio-medical engineering or the manufacturer's service engineer. All defective equipment must be properly labeled. After major adjustments, changes or repairs, equipment must be evaluated before use and inspected by the medical physicist according to 21 CFR 900.12(b) and (e). If the equipment cannot be repaired, it must be discarded properly.

(5) Computer Systems. FFDM computer systems (hardware and software) are to be validated at the time of installation and must be appropriately maintained to ensure they are functioning according to manufacturer's recommendations.

(a) New hardware must be validated at the time of installation and after any significant modification or change.

(b) New versions of software and changes ("patches") must be validated by the system manufacturer.

b. Printers and (Display) Monitors.

(1) The Chief of Radiology is responsible for ensuring all monitors used in the interpretation of mammography and all printers used by the program are FDA mammography-approved, comply with a QA program that is substantially the same as that recommended by the FFDM manufacturer, and pass the ACR's phantom and clinical image review process.

(2) Per the FDA, printing breast images to hard-copy film is no longer necessary and can be performed at the discretion of the mammography facilities. If a facility chooses to maintain a printer, it must follow all of the manufacturer's quality control requirements for both the printer and mammography unit. When a facility decides to maintain a printer, medical physicists must continue to include that printer QC in the Mammography Equipment Evaluation upon installation, after a major repair, and annually, if required by the printer's or image receptor's manufacturer quality control program.

c. Copiers and Digitizers.

(1) Only copiers or digitizers approved for mammography by FDA's Office of Device Evaluation are to be used for mammograms. The printer manufacturer can provide written documentation that the printer has been cleared by FDA for FFDM. The mammography program must implement QA procedures that are substantially the same as those recommended by the FFDM manufacturer. Phantom and clinical images

produced by such copying or digitization must pass all applicable QC tests and be of such quality that if they were submitted, they would pass the program's AB's review process.

(2) Programs are not to copy or digitize a screen film mammogram and use that copied or digitized image for retention purposes or final interpretation. Copied or digitized images of previously obtained mammograms may only be used for comparison purposes if the IP deems that acceptable. They cannot be used for final interpretation, nor can these images be used toward initial or continuing experience requirements.

d. **Image Compression: Lossless and Lossy.** Lossless compression accurately preserves all of the data from the original mammogram (image) and therefore images regenerated from lossless compressed data may be used in the same manner as the original mammogram.

(1) A program can use lossless compression to:

(a) Store FFDM images for retention purposes;

(b) Recreate FFDM images for final interpretation;

(c) Send lossless FFDM image data to an FDA (mammography)-approved laser printer, which can be used for final interpretation or comparison purposes; or

(d) Transmit images (data) to the patient or other medical institutions for final interpretation e.g., on CD/DVD, provided that such data transmission is acceptable to the receiving party and all VHA information security issues are addressed.

(2) A program cannot use lossy compression to:

(a) Store FFDM images for retention purposes;

(b) Recreate FFDM images for final interpretation; or

(c) Transmit images to the patient or other medical institutions for final interpretation.

(d) Images regenerated from lossy compressed data are not to be used in the same manner as the original mammogram. While not allowed for final interpretation, lossy compressed images of previously obtained mammograms may be transferred to the patient or another medical institution to be used for comparison purposes, if the IP deems that acceptable. Lossy image viewing or double-reading cannot be used toward initial or continuing experience requirements.

(e) If lossy compressed images are used for comparison purposes, only algorithms approved by FDA's Office of Device Evaluation for such purposes may be used. In addition, phantom and clinical images produced by lossy compression must be able to pass all applicable QC tests and be of such quality that if they were submitted, they would pass the program's AB's phantom and clinical image review process.

(f) If the program retains the mammogram in hard copy rather than electronic form, the hardcopy image must be of final interpretation quality.

e. **Digital Mammography Image Acquisition System Upgrades.** In the event that equipment is upgraded (same manufacturer) or the manufacturer is changed, the existing images must be backed up for retention purposes, and an acceptable method of accessing the images must be available. This is especially important when switching to a new equipment manufacturer, as the ability to access images produced by previous equipment must be maintained.

f. **Release of Images.** Many patients requesting the release of their FFDM exam need interpretation quality images created for them. The program may not charge for creating the first set of mammography images. However, if the patient requests additional copies of the mammogram, the program may pass the costs of the additional copies on to the patient, in accordance with release of information policies and guidance.

g. **Image Archiving.** Validation of active image archiving to both the primary Picture Archiving Communication System (PACS) long-term storage and back-up storage (e.g., VistA Imaging) should be performed according to National Archives and Records Administration in VHA Records Control Schedule (RCS) 10-1.

**VETERANS HEALTH ADMINISTRATION (VHA) MAMMOGRAPHY REPORT FINAL
ASSESSMENT CATEGORY: WORDING AND ASSOCIATED CODES**

Food and Drug Administration (FDA) required Mammography Report Final Assessment Categories: effective April 28, 1999	FDA Accepted Approved Alternatives: effective August 29, 2003	American College of Radiology equivalent BI-RADS numeric codes	VHA National Radiology Diagnostic Code
Negative	<i>Negative</i> Negative Mammogram	BI-RADS 1	1101
Benign	<i>Benign</i> Benign Finding Benign Findings Benign Abnormality Benign Abnormalities Benign Mammogram	BI-RADS 2	1102
Probably Benign	<i>Probably Benign</i> Probably Benign Finding Probably Benign Findings Probably Benign Abnormality Probably Benign Abnormalities Probably Benign Short Interval Follow-Up Suggested Probably Benign Finding – Short Interval Follow-up Suggested	BI-RADS 3	1103

Food and Drug Administration (FA) required Mammography Report Final Assessment Categories: effective April 28, 1999	FDA Accepted Approved Alternatives: effective August 29, 2003	American College of Radiology equivalent BI-RADS numeric codes	VHA National Radiology Diagnostic Code
	Probably Benign Mammogram		
Suspicious	<i>Suspicious</i>	BI-RADS 4	1104
	Suspicious Finding		
	Suspicious Findings		
	Suspicious Abnormality		
	Suspicious Abnormalities		
	Suspicious for Malignancy		
	Suspicious for Malignancies		
	Suspicious Abnormality – Biopsy Should Be Considered Suspicious Mammogram		
Highly Suggestive of Malignancy	<i>Highly Suggestive of Malignancy</i>	BI-RADS 5	1105
	Highly Suggestive for Malignancy		
	Highly Suggestive of Malignancy – Appropriate Action Should Be Taken		
Known Biopsy Proven Malignancy: Appropriate Action Should be Taken	<i>Known Biopsy Proven Malignancy: Appropriate Action Should be Taken</i>	BI-RADS 6	1106
	Known Biopsy Proven		

Food and Drug Administration (FA) required Mammography Report Final Assessment Categories: effective April 28, 1999	FDA Accepted Approved Alternatives: effective August 29, 2003	American College of Radiology equivalent BI-RADS numeric codes	VHA National Radiology Diagnostic Code
	Cancer Known Malignancy Known Cancer		
Incomplete: Need Additional Imaging Evaluation	<i>Incomplete: Need Additional Imaging Evaluation</i> Incomplete: Needs Additional Imaging Evaluation Incomplete: Additional Imaging Evaluation Needed Incomplete: Need Additional Imaging Evaluation Comparison with Prior Studies Incomplete: Need Additional Imaging Evaluation and/or Prior Mammograms for Comparison Incomplete: Need Prior Mammograms for comparison Need Additional Imaging Evaluation (the term "Incomplete" can be inferred in this example as this is the only Incomplete	BI-RADS 0	1100

Food and Drug Administration (FDA) required Mammography Report Final Assessment Categories: effective April 28, 1999	FDA Accepted Approved Alternatives: effective August 29, 2003	American College of Radiology equivalent BI-RADS numeric codes	VHA National Radiology Diagnostic Code
	BI-RADS assessment category		
	Incomplete Mammogram: Need Additional Imaging Evaluation		

BREAST TISSUE COMPOSITION CODES: WORDING AND ASSOCIATED CODES

Although VHA is not required to comply with State regulations, if your program is located in a State that has passed breast density legislation, programs may implement the breast density notification into their program. It is not mandatory that sites implement this process. Use of National Diagnostic codes for breast tissue composition is available and should be entered into the secondary diagnostic code field.

A Breast Density Reporting amendment to the Mammography Quality Standards Act (MQSA) is still under review by the FDA. If the FDA amends the MQSA regulations to a standardized nationwide notification in the lay letter patients receive after their mammogram, sites will need to comply with this change.

Breast Tissue Composition Description	Displayed Text in VistA	VHA National Radiology Diagnostic Code
The breasts are almost entirely fatty	ALMOST ENTIRELY FATTY	1111
There are scattered areas of fibroglandular density	SCATTERED AREAS OF FIBROGLANDULAR DENSITY	1112
The breasts are heterogeneously dense, which may obscure small masses	HETEROGENEOUSLY DENSE	1113
The breasts are extremely dense, which lowers the sensitivity of mammography	EXTREMELY DENSE	1114

ACCREDITATION DENIAL

If Accreditation is Not Granted

Attempt at Accreditation	Accreditation Result	Facility Options
1. First Attempt	<p><i>NOT GRANTED</i></p> <p>a. First deficiency.</p> <p>b. Facility may continue performing mammography with the unit as long as they have a valid certificate.</p>	<p>(1) <i>REPEAT</i> not acceptable area(s) (only if more than 60 days on certificate),</p> <p>(2) <i>REINSTATE</i> by retesting all areas (if 60 days or less on certificate),</p> <p>(3) <i>APPEAL</i> decision on original images, or</p> <p>(4) <i>WITHDRAW</i>.</p>
2. Second Attempt	<p><i>NOT GRANTED</i></p> <p>a. Second deficiency equals first failure.</p> <p>b. ACR strongly recommends that facility cease performing mammography with the unit.</p>	<p>(1) <i>REINSTATE</i> by retesting all areas (with corrective action),</p> <p>(2) <i>APPEAL</i> decision on original images (may not operate until the appeal is complete), or</p> <p>(3) <i>WITHDRAW</i>.</p>
3. Third Attempt	<p><i>NOT GRANTED</i></p> <p>a. Third deficiency equals second failure.</p> <p>b. ACR strongly recommends that facility cease performing mammography with the unit.</p>	<p>(1) <i>REINSTATE</i> after participating in Scheduled On-Site Survey (SOSS),</p> <p>(2) <i>APPEAL</i> decision on original images (may not operate until the appeal is complete), or</p> <p>(3) <i>WITHDRAW</i>.</p>