

MAMMOGRAPHY PROGRAM PROCEDURES AND STANDARDS

- 1. REASON FOR ISSUE.** This Veterans Health Administration (VHA) Handbook is issued to provide procedures for the administration, accreditation, staffing, and functioning of mammography programs in Department of Veterans Affairs (VA) facilities or facilities managed by VHA and community-based outpatient clinics (CBOCs) or leased facilities.
- 2. SUMMARY OF MAJOR CHANGES.** This revised Handbook contains updated implementation instructions and procedures for the administration, accreditation, staffing, and performance of mammography programs in VA facilities or those managed by VHA facilities, CBOCs and/or leased facilities). Facility implementation must be completed no later than September 30, 2011.
- 3. RESPONSIBLE OFFICE.** The Office of the Chief Consultant Diagnostic Services, National Radiology Program (115), is responsible for the contents of this Handbook. Questions may be addressed to (919) 383-7874, extension 261.
- 4. RESCISSIONS.** VHA Handbook 1104.1, dated August 6, 2003, is rescinded.
- 5. RECERTIFICATION.** This VHA Handbook is scheduled for recertification on, or before the last working day of April 2016.

Robert A. Petzel, M.D.
Under Secretary for Health

DISTRIBUTION: E-mailed to the VHA Publications Distribution List 5/3/2011

CONTENTS**VHA MAMMOGRAPHY PROGRAM POLICIES AND GUIDANCE**

PARAGRAPH	PAGE
1. Purpose	1
2. Background	1
3. Definitions	2
4. Scope	3
5. Overview of Mammography	4
6. Responsibilities of the Director, National Radiology Programs	5
7. Responsibilities of the VHA Mammography Office	6
8. Responsibilities of the National Mammography Advisory Committee.	6
9. Responsibilities of the Facility Director	7
10. Responsibilities of the Chief Radiology Service	9
11. Responsibilities of the Lead Interpreting Physician (LIP)	9
12. Responsibilities of the Interpreting Physician (IP)	9
13. Responsibilities of a Medical Physicist	10
14. Responsibilities of the Mammography Radiologic Technologist	10
15. Responsibilities of the Lead Mammography Quality Control (LMQC) Technologist	11
16. Mammography Program Documents Management	12
17. Accreditation, Certification, and Evaluation	12
18. Alternative Standards	14
19. Food and Drug Administration (FDA) Mammography Standards Inspections	14
20. Inspection Appeal Procedures	16
21. Medical Physics Surveys	17

CONTENTS Continued

PARAGRAPH	PAGE
22. Quality Assurance (QA)	18
23. Quality Control (QC) Program	18
24. Quality Administration Program	18
25. Patient Reports and Records Management	23
26. Additional Mammography Review (AMR)	30
27. Stereotactic Biopsy	30
28. Filmless (Digital) Mammography	32
29. Outsourced Mammography	35
30. References	36

APPENDICES

A Veterans Health Administration (VHA) Mammography Report Final Assessment Category	A-1
B Accreditation.....	B-1
C Elements to Be Addressed In a Mammography Agreement or Contract.....	C-1

MAMMOGRAPHY PROGRAM PROCEDURES AND STANDARDS

1. PURPOSE

This Veterans Health Administration (VHA) Handbook provides updated guidance and procedures for the performance and interpretation of Radiologic Mammography services in Department of Veterans Affairs (VA) medical facilities as required by Public Law (Pub. L.) and Federal regulations. It also provides procedures for the administrative structure and management of mammography services provided in VHA facilities and their outreach functions. This Handbook further defines requirements unique to VHA. Unless otherwise stated, requirements and guidance found in this Handbook are specifically intended for use and application for VHA in-house, on-site Mammography Programs.

2. BACKGROUND

a. Public Law 98-160, the Veterans' Health Care Amendments of 1983, was landmark legislation mandating VA to provide Veterans with preventive care. Because of potential benefit and the significant number of Veterans at risk, one of the preventive medicine program services chosen was breast cancer screening. Radiologic breast cancer screening is known as mammography.

b. On October 27, 1992, Congress passed Pub. L. 102-539, the Mammography Quality Standards Act (MQSA) of 1992. The Public Health Services Act (Title 42 United States Code (U.S.C.) 263b) was amended by the MQSA, which added Subpart 3, Mammography Facilities, Section 354. This amendment codified into law national quality standards for mammography. All Federal, State and private mammography facilities were included under the law except those of the Department of Veterans Affairs (VA), which were specifically excluded. After October 1, 1994, all non-VA facilities were required to be accredited by an approved accreditation body and certified to legally perform mammography. The Food and Drug Administration (FDA) of the Department of Health and Human Services (HHS) published implementing regulations for the MQSA, Title 21 Code of Federal Regulations (CFR) Parts 16 and 900.

c. Although VA facilities were initially excluded from coverage under the law, the VHA Under Secretary for Health chose to voluntarily adopt MQSA standards in VHA health care facilities providing mammography.

d. In 1996, the Congress affirmed the Under Secretary's decision by including VA health care facilities within the application of the law through passage of Pub. L. 104-262, the Veterans' Health Care Eligibility Reform Act of 1996 (38 U.S.C. 7319), Section 321. This law stated the Secretary of Veterans Affairs, in consultation with the Secretary, Health and Human Services (HHS), must publish mammography regulations to include that:

(1) Only VA facilities 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) may perform mammography.

(2) QA (QA) and quality control (QC) standards relating to the performance and interpretation of mammograms and use of mammography equipment in VA facilities must be consistent with the requirements of Section 354(f)(1) of the Public Health Service Act. Such standards are to be no less stringent than the standards prescribed by the Secretary, HHS, under Section 354(f) of the Public Health Service Act (see subpar. 2b).

(3) An annual inspection of the mammography equipment and services used in VA health care facilities must be performed by FDA. Inspections must be carried out in a manner consistent with the inspection of certified facilities by the Secretary, HHS, under section 354(g) of the Public Health Service Act.

***NOTE:** Pub. L. 104-262 requires VHA mammography facilities to meet the basic requirements of MQSA, but left the enforcement and oversight of on-site mammography facilities to VHA.*

e. The Veterans' Benefits Act of 1997 (Pub. L. 105-114), Section 208, November 21, 1997, codified at 38 U.S.C. 7322, required the VHA Under Secretary for Health to develop a national policy on mammography screening for Veterans. The law states that VHA policy must be in accordance with guidelines endorsed by the Secretary, HHS, and the Director of the National Institutes of Health (NIH).

f. The Mammography Quality Standards Re-Authorization Act of 1998 (Pub. L. 105-248), enacted October 9, 1998, revised MQSA and, most importantly, required the reporting of mammography results directly to patients in lay language, and the release of original mammogram films to the patient or their duly-authorized representative.

g. The mammography regulations (21 CFR Part 900) have been and continue to be modified over time. Rather than revising and publishing extensive VA regulations so that they are equal to, or more stringent than 21 CFR Part 900, this Handbook substitutes 21 CFR Part 900 where VA regulations do not provide explicit guidance.

3. DEFINITIONS

a. **Audit Interpreting Physician (IP).** An Audit IP must be a mammography qualified IP and must also be listed as an IP at the facility. At least one qualified IP must be designated to review the medical outcomes audit data.

b. **Facility.** Facility refers to VA medical facility, VA Health Care Systems (VAHCS), Independent Outpatient Clinic (IOC), any CBOC, or other health care delivery physical plant under VA auspices, which operates or wishes to operate an on-site Mammography Program.

c. **Full Field Digital Mammography (FFDM).** An FFDM utilizes low energy x-rays recorded by an electronic digital detector instead of the 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. **Lead Interpreting Physician (LIP).** The LIP is an IP assigned the general responsibility for ensuring that a facility's mammography 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 facility.

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

f. **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.

g. **“Other Qualified Personnel.”** “Other qualified personnel” means 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.”

4. SCOPE

a. Mammography is a specialty branch of diagnostic radiology where ionizing radiation is used to examine the breasts for the purpose of detecting breast cancer. Mammography IPs provide consultation and guidance to health care providers regarding mammographic technical findings and their implications.

b. A distinct subset of VHA health care facilities, Mammography Services have requested authority to commit their resources and expertise to performing diagnostic and screening mammography on-site.

c. VHA facilities authorized to perform on-site mammography must be certified through VHA. All other VA facilities must use certified off-site (non-VA) providers through contractual or sharing relationships, or fee-for-service basis. VHA Mammography Programs may range in complexity and configuration from an entire on-site program (screening and diagnostic mammography) with staff who are all VHA employees to an on-site program providing limited service using some combination of sharing agreements, locum tenens, contract and VHA staff. In some cases, VHA health care facilities may only receive mammography services performed by external off-site non-VA contract providers or fee-for-service providers.

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

e. At such point in time that Federal regulations and FDA guidance are publicized concerning interventional and other mammographic modalities, those regulations will also apply, to the extent possible, to VHA facilities certified to perform mammography.

f. 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. The abbreviations AB and ACR may be used interchangeably in this document but remain synonymous for VA purposes. Re-accreditation renewal occurs triennially. All VHA Mammography Programs must be accredited prior to any patient imaging. A program must be accredited before it can be certified. Successful accreditation and certification must be maintained to provide mammography services.

g. An annual mammography standards inspection must be performed by FDA-trained inspectors to assess whether or not the facility's program is meeting the requirements of 21 CFR Part 900.

h. An annual mammography physics survey, performed by a qualified medical physicist under the provisions of 21 CFR Part 900, must be completed for each program. The results must be reported to the individual requesting the survey so that corrective action(s) and follow-up, if needed, may be taken to ensure mammography standards and safety. At a minimum the mammography QC technologist must be provided a copy of the survey.

i. VHA retains exclusive oversight and enforcement responsibilities of its Mammography Programs through the Office of the Principal Deputy Under Secretary for Health, even though accreditation, mammography standards inspections, exam interpretation, procedure performance, and medical physicist responsibilities may be performed by independent third parties.

5. OVERVIEW OF MAMMOGRAPHY

a. The principles of quality mammography do not differ basically from those applicable to other radiological examinations. Key points to be considered are the criteria for credentialing professionals, equipment specifications, monitoring and maintenance schedules, standards for image quality, standardized image evaluation procedures, meticulous record keeping, and periodic review and feedback of data regarding outcomes of mammography interpretations.

b. Screening mammography is a radiological examination to detect unsuspected breast cancer at an early stage in asymptomatic women. The goal is to generate the best possible image quality at the minimal radiation dose necessary to give sufficient image information for accurate interpretation.

c. Problem-solving breast evaluation (diagnostic mammography and appropriate supplemental procedures) is intended to provide specific analytic evaluation of patients who have clinical signs or symptoms of breast disease, or screening-detected findings of concern. The diagnostic breast evaluation leads to definitive conclusions about the patient's symptoms or findings to enable specific management recommendations.

d. Breast interventional procedures' using stereotactic (mammographic) needle-targeting equipment ensures that patients receive optimum tissue sampling with the lowest possible risk. Stereotactic biopsy is an effective tool for breast cancer detection. Stereotactic core needle biopsy has been adopted to overcome the limitations of fine needle aspiration. Stereotactic biopsy offers the advantage of sufficient tissue for histologic diagnosis, specimen mammography, and hormone receptor analysis. For indeterminate lesions, stereotactically-guided core biopsy is a valuable technique and could decrease the need for excisional (open-surgical) biopsy.

e. Procedure results must be communicated to the ordering practitioner and patient, as outlined in Federal regulations, allowing prompt attention and appropriate clinical action to be taken. The ordering practitioner must communicate such test results to patients, so that they may participate in health care decisions.

f. The performance of mammography requires specific staff qualifications. Qualified mammography staff means all staff: LIP(s), Audit IPs, IPs, Mammography Technologists, and Medical Physicists must meet the initial and continuing personnel requirements as defined in 21 CFR 900.12(a).

6. RESPONSIBILITIES OF THE DIRECTOR, NATIONAL RADIOLOGY PROGRAMS

The Director, National Radiology Programs, is responsible for:

a. **Ensuring Accreditation.** All VHA Mammography Programs must maintain current accreditation with the ACR and successfully obtain approval to provide mammographic services by receiving VHA certification. Programs that perform mammographic procedures and fail to maintain current accreditation, programs which fail to meet national mammography standards requirements as described in 21 CFR Part 900, or programs which have demonstrated ongoing and uncorrected deficiencies may be instructed to terminate services or suspend those processes which are the basis of the failure.

b. **Recommending Denial, Revocation, Suspension, or Termination of Certification.** The Director, National Radiology Programs, 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 VHA policy. Facilities may appeal denial of certification directly with the National Director Radiology Program. The Principal Deputy Under Secretary for Health may approve, remand, or reject recommendations by the National Director Radiology Program.

c. **Designating VHA Mammography Programs of Excellence.** Some Mammography Programs may be designated as benchmark VHA Mammography Programs of Excellence. The primary goal of a Mammography Program of Excellence is to serve as a yardstick for other Mammography Programs and to facilitate the sharing of the capabilities, policies, and procedures available in these special Mammography Programs with other VHA programs. This is with the understanding that each Mammography Program possesses unique characteristics, constraints,

resources and opportunities. Best practices and success by a particular Mammography Program need to be positively recognized and adopted to the degree possible.

7. RESPONSIBILITIES OF THE VHA MAMMOGRAPHY OFFICE

The VHA Mammography Office (VHAMO) under the National Radiology Program, VA Central Office, has the responsibility for:

- a. Collecting and analyzing compliance data from all VHA on-site Mammography Programs. On a routine basis, mammography inspection and accreditation results are provided by VHAMO to the individual facilities and National Director Radiology for use in program improvement, compliance, and oversight activities.
- b. Providing recommendations on interpretation of regulatory requirements found in Federal statutes, regulations, and guidance pertaining to mammography quality standards.
- c. Preparing recommendations to Veterans Integrated Service Networks (VISNs) on the baseline requirements for program establishment, continuation, or closure.
- d. Developing recommendations to the National Director, Radiology Program, concerning program certification; i.e., granting, extension, revocation, suspension, or denial.
- e. 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.

8. RESPONSIBILITIES OF THE NATIONAL MAMMOGRAPHY ADVISORY COMMITTEE

a. The National Mammography Advisory Committee, chaired by a LIP who serves in an expert advisory capacity to the Director, National Radiology Programs (115), is comprised of qualified mammography individuals who have vested interests in VHA's breast imaging quality and responsive health care delivery. These include:

- (1) IP(s);
- (2) Technologist(s);
- (3) Medical Physicist(s);
- (4) Representatives of both the VA and VHA Women Veterans Health Program; and
- (5) Others as may be necessary.

b. The committee's primary functions are to:

- (1) Assess the quality of the performance of mammography in VHA Radiology settings.

(2) Annually review the goals, plans, successes, failures, and opportunities or areas for improvement of breast imaging services to Veterans.

(3) Recommend contractual inclusions or exclusions for VHA facilities outsourcing mammography.

(4) Recommend actions, which may be no less stringent than national mammography standards in elevating VHA mammography to the highest levels.

(5) Recognize outstanding Mammography Programs offering special expertise, e.g., equipment utilization, policy application, program management, or procedure performance to other VA medical centers with in-house Mammography Programs.

(6) In special situations:

(a) Review selected annual reports,

(b) Participate in site visits to Mammography Programs, and

(c) Advise the Director, National Radiology Programs, on selected issues.

9. RESPONSIBILITIES OF THE FACILITY DIRECTOR

The facility Director is 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, implemented, and patterned after the ACR practice guidelines and the ACR QC manual.

10. RESPONSIBILITIES OF THE CHIEF, RADIOLOGY SERVICE

The Chief Radiology Service, or Chief Radiologist is responsible for:

a. **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 conformance and compliance with VHA imposed measures and monitors, critical results communication, credentialing, etc.

b. **Mammography QA Program.** The mammography QA program and each of its elements shall only be assigned to individuals who are qualified for their assignments and who shall be 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 for mammography, 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.

c. Mammography Programs with VHA Interpreting Physician Staff

- (1) The Chief Radiologist designates a LIP who has the responsibility of ensuring that the QA program meets Federal requirements.
- (2) 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.
- (3) 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.
- (4) The Chief Radiologist must issue a statement of responsibilities. Because the regulations (MQSA, 42 U.S.C. 273b, Sec. 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 facility does not have to restate the responsibilities of the program individuals. However, if the 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 qualifications for that individual(s) must be provided.

d. Mammography Programs with Non-VHA IP Staff

- (1) 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.
- (2) 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:
 - (a) 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.
 - (b) A statement of responsibilities. Because the regulations already specify the responsibilities of the LIP, medical physicist(s), QC technologist(s), and Audit IP(s), the responsibilities of these program individuals does not need to be restated; however, 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.

e. Ensuring for Non-VHA Interpreting Staff

- (1) Quality patient services must be provided, and personnel operations and program management must run smoothly and efficiently. This may be delegated to the LIP.
- (2) Required policies and procedures must be developed, published, updated, and followed to ensure compliance with Federal and VA requirements. Mammography

programs outside VA, are certified (nationally) under the direction of the Food and Drug Administration (FDA) pursuant to Pub. L. 102-539 and Pub. L. 105-248. In order to qualify for certification, a facility must be successfully accredited and maintain that accreditation, pass an annual survey by a qualified medical physicist, and undergo (pass) annual mammography standards inspections.

(a) Non-VA facilities may be certified by the:

1. FDA, or
2. State of Iowa for sites within that state, or
3. State of Illinois for sites within that state, or
4. State of South Carolina for sites within that state. (per the Federal Register, 7/7/05, vol. 70, No. 129, pg. 39266.

(b) A non VA facility may be accredited by any one of the following:

1. American College of Radiology (ACR), or
2. The State of Arkansas for facilities within that state, or
3. The State of Iowa for facilities within that state, or
4. The State of Texas for facilities within that state.

11. RESPONSIBILITIES OF THE LEAD INTERPERTING PHYSICIAN (LIP)

The LIP must be a mammography-qualified IP. The LIP is responsible for:

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

b. 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.*

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

d. Participating in the triennial accreditation renewal process, the annual FDA inspection, and any other review of mammography quality within the program or required under Federal regulations (see MQSA 263b, 24 CFR 900.12 (d)(1)).

e. 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.*

f. 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.*

12. RESPONSIBILITIES OF THE INTERPRETING PHYSICIANS (IP)

IPs are the physicians who interpret mammograms; they are responsible for:

a. Providing consultation to referring clinicians regarding the medical significance of the clinical images.

b. Ensuring the quality of mammography images they interpret and the content of the reports they verify. IPs need to provide frequent and consistent feedback, following facility and Service policies, concerning the images they are asked to interpret.

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

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

c. Participating in the facility's mammography medical outcomes audit program.

NOTE: *Non-VHA IPs also provide feedback on image quality and QC practices to the Chief Radiologist; and participate in the facility's (mammography) medical outcomes audit program. Feedback with regard to IP performance must be provided to the Chief Radiologist.*

13. RESPONSIBILITIES OF A MEDICAL PHYSICIST

A qualified medical physicist's services are required to survey mammography equipment and oversee the equipment-related QA practices of the program. The medical physicist is responsible for:

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

- b. Providing the program with a report of the annual survey.
- c. Ensuring mammography equipment evaluations (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). **NOTE:** *Non-VHA physicists are required to comply with the same requirements in reference to mammography as a VA physicist*

14. RESPONSIBILITIES OF THE MAMMOGRAPHY RADIOLOGIC TECHNOLOGIST

The radiologic technologist's responsibilities center on patient care and image quality. More specifically, these include:

- a. Patient positioning;
- b. Compression;
- c. Image acquisition;
- d. Film processing;
- e. Infection control; and
- f. Ensuring that all assigned QC and QA tasks are performed in a professional, traceable, and verifiable manner.

15. RESPONSIBILITIES OF THE LEAD MAMMOGRAPHY QUALITY CONTROL (LMQC) TECHNOLOGIST

Responsibility for all individual tasks within the QA program not assigned to the LIP or the Medical Physicist must be assigned to a 'qualified' LMQC technologist. **NOTE:** *For programs with only one mammography technologist, that person will be the LMQC technologist.*

Normally, they are 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.* The LMQC Technologist is responsible for:

- a. Apprising program staff of new mammography standards and modifications to existing mammography standards and guidance authored by VHA, FDA, ACR, etc., and acting as a resource to the LIP.
- b. Ensuring that each program has current copies of pertinent VHA Handbooks, Standard Operating procedures (SOPs), and guidance documents dealing with mammography to include: inspection, accreditation requirements, equipment QC, and the proficiency programs.

- c. Being the contact point for the FDA mammography standards inspections, in the absence of, or as a designee of, the Chief Radiologist or LIP.
- d. Analyzing inspection reports of the program to identify problems and trends, and reporting this information to appropriate facility management and the Chief Radiologist.
- e. 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.
- f. Reviewing investigation reports from the FDA, ACR, Inspector General (IG), and Medical Inspector (MI) dealing with the Mammography Program, and following up with the Chief Radiologist and the LIP to ensure that issues are identified for timely correction.
- g. Advising the Chief Radiologist and LIP of problems and concerns affecting the quality of the work in the program.
- h. 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.
- i. Reviewing records (see subpar. 16b).

16. MAMMOGRAPHY PROGRAM DOCUMENTS MANAGEMENT

The LIP, LMQC technologist, and medical physicist are responsible for ensuring that records concerning mammography technique and procedures, quality control (including monitoring data, problems detected by analysis of that data, corrective actions, and the effectiveness of the corrective actions), safety, protection, and employee qualifications to meet assigned QA tasks, are properly maintained and updated.

a. **Record Keeping.** A system for generation, retention, storage, and retrieval of all required mammography records must be maintained; this is to ensure:

(1) Records are completed according to instructions in the relevant SOPs or policies, which are derived from Pub. L., Federal regulations, and VA policies.

(2) 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.

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

b. **Record Review.** Each program must ensure that all records relating to mammographic QA, peer review, medical audits, calibrations, and physicist inspection are reviewed in a manner and on a schedule by the LMQC, Lead Radiologist, or physicist to ensure the records meet the most stringent requirements of VA, FDA, or the accrediting body.

c. **SOP Documents.** A comprehensive policy and SOP manual, developed by each Mammography Program, covering critical functions (technical, clerical, and administrative) performed by the program must be maintained.

(1) The SOP documents must be current in order to reflect the actual practices in the program.

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

(3) The SOP documents must be readily available to all Mammography Program staff.

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

17. ACCREDITATION, CERTIFICATION, AND EVALUATION

A VHA facility interested in establishing a program and performing mammography on-site must apply for and attain accreditation from an approved non-profit AB that meets the requirements of 21 CFR Part 900 and 38 U.S.C. 7319(a). VHA mammography facilities cannot use the FDA or FDA-approved States as accreditation certifiers. ACR meets all the criteria required for use by VHA. All VHA Mammography Programs are required to register with the National Radiology Program, VHAMO and be issued a VHA certification number.

a. **Certification**

(1) Each independent VHA facility-based Mammography Program must be accredited and issued a separate number.

(2) VHA Mammography Programs are required to revalidate their certificate with the VHAMO after every successful triennial 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.*

b. **Accreditation.** Accreditation procedures placed into effect by the AB, the requirements of 21 CFR 900 and 38 U.S.C. 7319(a), and requirements to become certified must be followed by VHA Mammography Programs. Programs need to allow from 6 – 8 months for the re-accreditation process. A program generally has 45 calendar days from the date the testing materials are received by the program to return the completed application and testing materials (including images) to the ACR.

c. **Accreditation Denial.** The AB 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 App. B for the Accreditation table).

d. **AB Clinical Image Review.** The clinical images submitted to the AB 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.’

e. **External Proficiency Assessments.** To ensure quality of clinical images in the program and to maintain certification, each program must undergo AB evaluations, FDA compliance inspections, and medical physics surveys; as found in 21 CFR Part 900.

f. **Fees**

(1) 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 facility Mammography Program.

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

(3) Costs and fees associated with the retention of qualified contract or fee medical physics services as required by Federal regulations are the responsibility of the respective facility Mammography Program.

18. ALTERNATIVE STANDARDS

An alternative standard is a means to ensure quality mammography replaces or augments existing regulatory standards. Alternatives 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 VHA facilities, unless otherwise precluded by VHA policy.

a. **Processing Proposals.** A proposed alternative standard needs be developed following the guidelines found in 21 CFR 900.18 and submitted to the National Radiology Program, VHAMO, Suite 200, 3022 Croasdaile Dr., Durham, NC 27705, for review and assessment.

b. **Review.** When a request is received it is reviewed by the National Mammography Advisory Committee. Proposals with merit are referred to FDA for further comment(s) prior to approval or implementation.

c. **Approval or Denial.** The National Director, Radiology Program, through the Chief Consultant, Diagnostic Services, or designee, may recommend approval or denial, in whole or in part, regarding 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.

19. FOOD AND DRUG ADMINISTRATION (FDA) MAMMOGRAPHY STANDARDS INSPECTIONS

VHA has entered into an IAG 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

a. **Mammography Standards Inspections.** Mammography standards inspections cover the following areas:

- (1) Equipment performance (including image quality (phantom) and radiation dose measurements);
- (2) Technologist and physicist QC and QA tests, tasks, and records;
- (3) Medical audit and outcome analysis records;
- (4) Medical records, mammography reports, and images; and
- (5) Personnel qualification records.

b. **Violations**

(1) Violations are categorized into four levels. 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, as categorized in the following:

(a) **Level 1 (L1); Level 1-Repeat.** Level 1 is 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) **Level 2 (L2); Level 2-Repeat.** In the absence of L1 violations, a L2 violation indicates that the program meets all key requirements, but fails to meet significant mammography quality items.

(c) **Level 3 (L3).** In the absence of L1 and L2 violations, L3 violations indicate that the program meets all major requirements with minor exceptions.

(d) **No Violations (Full Compliance).** The program meets national mammography standards as denoted by FDA. No action is required.

(2) Each Mammography Program LIP with L1 or L2 violations must prepare a written response, through their respective medical facility Director to VHAMO, outlining the program's corrective action plan to resolve the violation(s).

(a) 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 generally is not required to send a written response concerning L3 violations.

(b) Corrective actions regarding all violations, level notwithstanding, are checked during the next annual inspection to ensure resolution.

c. **Corrective Action Plan**

(1) A corrective action plan consists of:

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

(b) Specific actions taken to prevent reoccurrence; and

(c) Evidence that the problem has been corrected.

(2) The number of violations, the severity level, context of the violations, inspector remarks, etc., may also indicate that additional steps need to be taken. The National Director 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:

(a) Removing equipment from use;

(b) Recalling patients improperly exposed;

(c) Re-reading mammograms;

(d) Suspending the performance of mammography;

(e) Closing the program;

(f) Providing additional documentation;

(g) Implementing further corrective action; or

(h) Ensuring additional staff training, as deemed appropriate, to resolve the violations.

(3) 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., AMR, site visit, etc., 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:

- (a) There is no immediate jeopardy to patient health and safety.
- (b) 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.
- (c) The 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 prevent violation reoccurrence. *NOTE: The VHAMO may request submission of evidence of the quarterly reviews to verify actions and progress.*

20. INSPECTION APPEAL PROCEDURES

The National Director, Radiology Program, is responsible for overseeing performance and follow-up with the individual programs to ensure that 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.*

- a. It is important to document, with photo copies (if pertinent), the items and issues the inspector cited. *NOTE: Consider in retrospect, unless originals or maintaining copies of the originals, it would be difficult if not impossible to recreate the environment, issues, and other variables in place on the date of the inspection without proper documentation.*
- b. Any correspondence including an appeal must be submitted through appropriate medical center channels and is to include:
 - (1) A copy of the inspection violations and results report;
 - (2) A clear statement of the accepted issue(s);
 - (3) Reference(s) to any mammography standards, final mammography regulations, excerpts from guidance documents, etc., which 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 removing the cited violation(s). VHA apprises FDA of the final outcome of the review.

21. 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 must be performed using technique factors and test conditions as stated in the regulations, whenever those factors are specified. Otherwise, technique factors that are clinically used in the program must be utilized.
- c. **Survey Appeal Procedures.** Issues with test performance, survey conduct, report content, etc., need to be directed to the qualified medical physicist or Acquisition and Materials Management Service (A&MMS) if contract medical physicist services are used.

22. QUALITY ASSURANCE (QA)

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. QA program content must be in accordance with 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. QA activities include the employment, training, and continuing education and continuing experience of qualified personnel. QA activities may be subdivided into two major categories: QC procedures and Quality Administration procedures.

23. QUALITY CONTROL (QC) PROGRAM

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.

- a. 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: 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.

- b. Documentation must be maintained at least in between inspections. QC documentation must be securely retained for a minimum of two successive FDA 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 problem is corrected and the records have been subsequently reviewed by the FDA inspector during three successive inspections.

24. QUALITY ADMINISTRATION PROGRAM

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, participating with intra- and inter- facility efforts to improve patient care tracking, and follow-up.

a. **Infection Control and Program Cleanliness.** All VHA Mammography Programs are required to:

(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 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, at least for FDA inspector reference.

b. **Image Viewing Considerations.** Image viewing includes:

(1) **Screen-Film and View Boxes.** 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.

(a) 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.*

(b) If a separate viewbox 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.

(2) **Digital Monitors and Display Stations.** Only monitors specifically approved or cleared for FFDM use by FDA's Office of Device Evaluation are used by VHA programs in the interpretation of mammograms.

(a) 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: At the current time, no AB reviews soft copy images, so FDA recommends that the soft copy images be of such quality that if they were submitted they would pass the AB's phantom and clinical image review process.*

(b) Each softcopy and hardcopy mammographic image used for final interpretation must be consistent with 21 CFR 900.12(c)(5) and indicate identifying information, including view and laterality, technologist identification, patient name, etc.

c. **Medical Outcomes Audit.** A comprehensive mammography quality assessment program not only evaluates equipment, image quality, and image processing, but also evaluates the appropriateness and accuracy of image interpretation. Aggregate medical outcomes audit data provide a picture of how the program is detecting breast cancer among its patients. Individual analyses are important to identify IPs who have outcomes that are very different from the aggregate.

(1) 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.

(2) The mammography medical audit system must be able to document:

(a) The identification of the Audit IP(s).

(b) 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."*

(c) A method established by the LMQC technologist to follow-up mammograms identified as 'positive' with the auditing IP.

(d) 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.

(e) 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 Illustrated Breast Image Reporting and Data System Manual for information regarding recommendations for the collection of data.*

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

(4) 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. **NOTE:** *the intent of (mammography) medical audit outcomes tracking is for IP quality improvement, not to ensure the patient's ordering practitioner is addressing continued follow-up and treatment based on the communicated results. Other monitors and measures outside Radiology may be appropriately mandated to monitor the effectiveness and continuity of patient care after the procedure results are communicated to the ordering practitioner. Aggregate (mammography) medical outcomes audit data provide a picture of how the program is detecting breast cancer among its patients. Individual analyses are important to identify IPs who have results that are very different from the aggregate, which may suggest opportunities for additional education or training to improve interpretive accuracy.*

d. **Breast Implants**

(1) Each Mammography Program must develop and publish written positioning and technical procedures that 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

(2) 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.

e. **Consumer Complaint Process**

(1) 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 the instructions that are, or would be, provided to patients describing how to proceed with referral of serious unresolved complaints to the AB. The established procedures must meet the requirements of 21 CFR 900.12(h).

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

- (a) Poor image quality,
- (b) Missed cancers,
- (c) The use of personnel who do not meet the applicable requirements of 21 CFR 900.12(a), and
- (d) Failure to send mammography reports or lay summaries to the appropriate person(s) within 30 days.

(3) The program is required to maintain a record of each serious complaint.

(a) 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.

(b) 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.

NOTE: 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, and requesting that patients complete a comment card following the mammography exam. FDA encourages the facility to train its staff 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 medical facility's patient representative or patient advocate, may handle complaints for the Mammography Program if it is part of the facility's written procedure for addressing complaints.

f. **Repeat Analysis**

(1) The concept of repeat analysis is sound for both mammography modalities; screen-film and digital. The rationale for performing the analysis is to evaluate reasons for repeated mammograms. As equipment becomes more sophisticated, repeated mammograms due to equipment causes become less of an issue and FFDM has eliminated some problems. However, the main reasons for repeats usually come from technologist performance. A switch to FFDM won't fix poor positioning or inadequate compression. Training or a change in behavior is the answer which is unrelated to equipment.

(2) Under FFDM, the QA requirements focus is switched from the regulations to the FFDM 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, which means looking for the same type of records that the program would keep for film units consistent with 21 CFR 900.12(e)(3).

(3) If the total repeat, or reject, rate changes from the previously-determined rate by more than 2.0 percent of the total films 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.

25. PATIENT REPORTS AND RECORDS MANAGEMENT

a. **Patient Reports**

(1) **Inclusion in VistA.** All mammography reports regardless of where the procedure(s) are performed (in house, other certified VHA Mammography Program, contract provider or Fee Basis provider 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 App. A).

(2) **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). **NOTE:** *The use of voice recognition (VR) is encouraged to speed report generation and results distribution.* Reports must be entered into the Radiology Package of VistA. 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 according to the table in Appendix A, allowing activation of Clinical Reminders and Alerts in the Computerized Patient Record System (CPRS).

(3) **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 Radiology Package of VistA. If reports are received as hardcopy, they must be scanned into VistA Imaging and linked to an administrative report in VistA. The administrative report is a placeholder that states words to the effect that "an outside hardcopy mammography report has been scanned into VistA Imaging." 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 A. The process of choosing the correct Diagnostic Code can be simplified if the contract mammographer is required to dictate the numerical ACR BI-RADS code in the report.

b. **Dictation Timeliness.** As with any imaging study and according to VHA Policy, the interpreted mammogram must be reported with in 48 hours.

(1) **In-house Reports.** In-house reports are to be completed within 48 hours.

(2) **Outsourced Reports.** Facilities are encouraged to negotiate report turnaround times into contractual arrangements and take necessary steps to attempt to obtain timely reports from Fee basis providers who supply imaging for VHA Veterans at VHA expense.

c. **Report Content**

(1) 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.*

(2) The mammography report content must include:

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

(b) Date of examination,

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

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

(3) 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.

(4) 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 must be addressed in the report to the extent possible, even if the assessment is negative or benign.

d. **Final Assessment Report Categories.** FDA requires that a final assessment category be provided for each mammography report. This is not a new requirement and each VHA,

Department of Defense (DOD), and public or private sector Mammography Program must provide a final assessment category within the 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. **NOTE:** Final Assessment Category wording and the FDA acceptable word substitutions are found in Appendix A. Reporting only a BI-RADS numeric code alone does not meet the FDA requirements of providing an overall final assessment category.

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

- (1) BI-RADS code 1 (Negative), indicates there is no mammographic evidence of malignancy.
- (2) BI-RADS code 2 (Benign), indicates there is no mammographic evidence of malignancy.
- (3) 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.*
- (4) BI-RADS code 4 (Suspicious) and 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.
 - (a) 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 code 3. Thus, most recommendations of breast interventional procedures would be placed within this category. Further subdivision of BI- RADS code 4 is encouraged by ACR, but not required by FDA.
 - (b) 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.
- (5) 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.
- (6) 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. Under no circumstances will a mammogram interpretation be delayed beyond the 48 hours due to lack of comparison studies.

(a) There are three general scenarios where 'Incomplete' may be used:

1. First, the need to obtain additional mammographic images (e.g., magnification views) to complete the work up;
2. Second to obtain non-mammographic images (e.g., breast Magnetic Resonance Imaging, MRI) to complete the work-up; or
3. Third needing prior mammograms for comparison purposes.

(b) 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.

f. **Additional Mammographic Images**

(1) **Same Day.** Under new Centers for Medicare and Medicaid Services (CMS) guidelines (see <http://www.cms.gov/home/regsguidance.asp>) a program can claim screening and diagnostic exams done on the same patient on the same day. The report issued after additional mammographic testing (e.g., coned, repeat, 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:

- (a) A single combined report, must contain a single overall final assessment.
- (b) The combined report, needs to make it clear 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.
- (c) Issuing a single report with a single final assessment, may skew the Mammography Program's medical audit results.
- (d) Though some computerized reporting systems may consider this a single exam (rather than two), FDA still allows facilities to count both exams toward meeting the continuing experience requirement.

(2) **Patient Re-scheduled.** If the patient must be scheduled to return, 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 these (additional) views must issue a report reflecting the final assessment.

g. **Additional Non-Mammographic Images**

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

(2) 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.

h. **Prior Film or Image Comparison.** The report issued following comparison with prior films or images needs to 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 to the patient, just as any other report would be communicated.

(1) Screening mammography is utilized for asymptomatic patients. Comparison images maybe helpful to decrease the need for patient recall, however, prior comparison images are not always required to interpret mammograms and may not be available. Delaying interpretation of mammograms while waiting for the retrieval and receipt of prior images which may be lost, or may never have existed or which may never be obtained, is not recommended. The exam interpretation must be completed within 48 hours based on the images available and modified (by amendment) later, if and when comparison films or images become available. An important factor in considering program practice is to at least meet, if not exceed, the standard of care in the community and to avoid unnecessary litigious exposure through delayed diagnosis.

(2) The reasons why no assessment can be made and the recommendations to the ordering practitioner should detail the suggested workup (e.g., additional views or ultrasound) needed if prior images are not received.

i. **Report Addenda.** The report issued after additional testing that is covered under MQSA (e.g., coned, repeat, magnification views), or following comparison with prior images, needs to reflect the final assessment category for the case following these additional mammographic procedures or comparison studies.

(1) A report of this nature 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.

(2) 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.

(3) If the “addendum” merely stated that the ordering practitioner had been notified of the results of the patient’s examination, the addendum lay summary could be a simple statement informing the patient of that fact.

(4) Report completion within 48 hours also applies to amended reports.

j. **Communication of Results**

(1) 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.

(a) It is the IP's responsibility to interpret the images, the mammogram results, and any positive findings, which are to be made known 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.

(b) If the VHA ordering practitioner and the VHA Mammography Program are co-located within the same facility, one written communication provided to the patient meets FDA's intent to notify the patient of the exam's results. There is no need for both the ordering practitioner and the Mammography Program to duplicate efforts and separately provide redundant written communication of the exam results. The communication of results to the patient does not obviate the potential need by the ordering practitioner to discuss additional care issues with the patient. Although facility policy needs to be clear on who is to send the results letter, the details of such a system are left to the program and the facility in which it resides.

(c) When mapping out a system or process to communicate the mammogram results, facility management needs to take into consideration the Mammography Program's specific and unique organizational characteristics within the facility structure, its limitations, and its resources.

(2) **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.

(a) 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 no more than 5 business days. FDA's intent is to address women's 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.

(b) 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 exceed the local community standard of care, or comply with other VA Central

Office policy documents. This is especially true where the results are "suspicious" or "highly suggestive of malignancy."

(c) Computer-generated lay summaries are acceptable under the final regulations. The facility may develop appropriate procedures for providing these lay summaries to their patients. Until VHA has approved secure messaging systems established, no patient identifiable information is to be communicated to patients by email. When electronic means can't achieve protected communication, hard copy (paper) lay summaries must be provided.

(3) Communication to Ordering Practitioners

(a) The signed written report must be provided to the ordering practitioner within 30 days of the examination date. 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.

(b) 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 no more than 3 business days. The IP is to make reasonable attempts to ensure the ordering practitioner is promptly contacted with the mammography results, in concert 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.

k. **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 (see subpar. 25i).

1. Retention, Release, and Labeling

(1) VHA RCS 10-1 contains the 10-year retention period for mammography film or images. The Privacy Act, etc. and other internal VHA policy, including RCS 10-1 provide direction and guidance concerning the retention of other records.

(2) Generally, the Privacy Act regulations cover release of mammograms and patient medical information. However, there are two sections of the record keeping requirement that are affected by the introduction of FFDM.

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

(b) The second section affected by FFDM deals with transferring films or images. For purposes of transferring films, the program must be able to provide the medical institution, physician, health care provider, patient, or patient's representative with hardcopy films of final interpretation quality or, when it is acceptable to the recipient (e.g., a transfer between two FFDM facilities), with original or lossless compressed full-field digital images electronically; see the Filmless (Digital) Mammography par.28 for additional information).

(c) The 'original' mammograms and copies of the patient's reports must be transferred to the patient's designated recipient after receipt of an appropriately-executed written release of information request by the patient (or an authorized person acting on the patient's behalf). Patients and their representatives need to follow Privacy Act and VHA policy provisions concerning the release of information. **NOTE:** *Facilities need to be aware that the Federal law pertaining to transfer of original mammograms in accordance with 21 CFR 900.12(c) supersedes any conflicting facility requirements.*

m. **Image Identification.** Each softcopy and hardcopy mammographic image used for final interpretation must indicate identifying information, including view and laterality, technologist identification, patient name, etc. consistent with 21 CFR 900.12(c)(5).

26. 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 there from, appropriate remedial measures, and such other relevant information as VHA may require. Such notification must occur within a timeframe and in a manner specified by the Office of the Principal Deputy Under Secretary for Health.

27. STEREOTACTIC BIOPSY

Stereotactic Biopsy is the performance of stereotactically-guided breast interventional procedures using an add-on unit to the mammography machine or a dedicated prone table mammographic stereotactic biopsy system.

a. **Background.** ACR has published a practice guideline, “The Performance of Stereotactically Guided Breast Interventional Procedures,” a Stereotactic Breast Biopsy QC Manual and has established a Stereotactic Biopsy Accreditation Program. Currently stereotactic interventional procedures of the breast are exempt from the definition of mammography and the requirements of the final mammography regulations. However, mammography equipment is utilized to determine that proper stereotactic targeting and intervention have occurred. Since mammography equipment is used in these procedures, it logically follows that the same assurances are to be provided and care taken to determine the accuracy, maintenance, and functioning of this equipment.

b. **Scope.** When the Federal law and standards cover mammographic stereotactic breast interventions, all VHA facilities providing on-site stereotactic breast interventions must meet those standards. Facilities that choose not to meet the Federal standards must cease performing stereotactic procedures on-site.

c. **On-site Breast Interventions.** VHA meets the requirements found in the ACR Practice Guideline for Stereotactically Guided Breast Interventional Procedures; ACR’s Stereotactic Breast Biopsy QC Manual. ***NOTE: If possible participation in the ACR’s Stereotactic Biopsy Accreditation Program is strongly encouraged.***

d. **Outsourced Breast Interventions.** All VHA facilities that outsource stereotactic breast procedures must obtain the procedures from accredited providers. If an accredited provider is not available in the community, then the VHA facility must document that fact, as well as what actions have been taken to determine the availability of an accredited site, and how quality patient care will be ensured by a non-accredited provider. ***NOTE: Two organizations, the American College of Radiology and the American College of Surgeons, both accredit Stereotactic Breast Biopsy programs.***

e. **Transportation of Patients Undergoing Open Breast Biopsy After Needle Localization.** The biopsy procedure needs to be performed at the same facility as the mammographic needle localization, preferably in the same building. Transportation by motor vehicles or across considerable distances is to be avoided, unless other reasonable options do not exist, and the benefit to the patient is judged to exceed the risk of inadvertent wire dislodgement and resultant non-diagnostic or false negative biopsy.

(1) After confirming position of the localizing needle, a protective cup-like shield or similar stabilizing structure is to be carefully affixed over the protruding portion of the localizing needle, to the surrounding breast or chest wall with adhesive strips to minimize movement.

(2) The patient is to remain, as far as is feasible, in the position in which the localizing needle was inserted (i.e., seated, supine, etc.) during transport to the operating suite.

(3) Patient comfort and modesty concerns are to be adequately addressed. Blankets and outerwear must be carefully applied and immobilized to avoid any needle movement.

(4) The patient is to avoid moving the ipsilateral arm. Examining gowns need to be draped over, or secured around, the patient's shoulder and arm. The patient is not to attempt to pass an arm through a garment.

(5) The procedure is to be coordinated in advance by radiology and surgery to avoid unnecessary delay in actual performance of the biopsy after the localization procedure is complete.

f. **Records Tracking.** Records are to be kept of the number of cancers diagnosed and the number of complications requiring treatment. The numbers of inconclusive results, inadequate samples, and recommendations for re-biopsy or complete excision of a lesion also are to be recorded.

(1) Imaging findings and pathologic interpretations need to be correlated and provisions made for review and physician feedback of these findings.

(2) Biopsy follow-up is to be performed to detect and record any false-negative and false-positive results. As with all interventional procedures, the procedure must be fully explained to the patient, including the relative risks, benefits, limitations, and alternatives.

g. **Policies and Procedures.** Policies and procedures related to quality, patient education, infection control, and safety must be developed, implemented, and patterned after the ACR practice guidelines and the ACR QC manual.

28. FILMLESS (DIGITAL) MAMMOGRAPHY

Digital mammography offers many potential advantages over conventional screen-film techniques, particularly in image display, transmission, and processing. 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 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 number and the IFU to confirm FDA approval.

(1) **Calibration.** Calibration must be performed by a qualified medical physicist on all new equipment, after each repair, and on a schedule in conformance with all regulatory requirements and accreditation standards.

(a) Calibration is performed according to procedures defined by the manufacturer.

(b) Calibration documentation must be maintained, including equipment identification (ID), calibration results, actions taken (i.e., equipment disposition), and follow-up.

(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, actions taken (i.e., equipment disposition), and follow-up.

(3) QC

(a) QC is performed by the Medical Physicist or LMQC on each type of equipment based on manufacturer's recommendations, regulatory requirements, accreditation standards, and internal requirements.

(b) Quality control 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 repair, all equipment must be calibrated before use and inspected by the medical physicist. 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 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 Radiologist 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. **NOTE:** *At the current time, no AB reviews soft copy images, so FDA recommends that the soft copy images be of such quality that if they were submitted they would pass the ACR's phantom and clinical image review process.*

(2) The image display device(s) used by the technologist(s) to check the quality of the mammography images is to approach the image display parameters (5K x 5K) of those used by the IPs and be in a setting where the ambient lighting conditions are similar to where the mammograms are interpreted. **NOTE:** *Each softcopy and hardcopy mammographic image used for final interpretation must indicate identifying information: including view and laterality, technologist identification, patient name, etc., and be consistent with 21 CFR 900.12(c)(5).*

(3) Although a program may exclusively use soft copy for final interpretation, it must be able to produce final interpretation quality hard copy images for those patients, their representatives, and health-care providers who request hard copy transfer of the mammogram study. Therefore the program needs access to an FDA mammography-approved printer. The FDA-approved printer is subject to the performance of all required QC testing on the laser printer.

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 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 are able to 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 (film) 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

(1) A program can use lossless compression to:

(a) Store FFDM images for retention purposes.

(b) Recreate FFDM images for final interpretation.

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

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

(2) 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.

(a) Lossless FFDM image data sent to an FDA (mammography)-approved laser printer, may be used for final interpretation or comparison purposes.

(b) A program cannot use lossy compression to:

1. Store FFDM images for retention purposes,
2. Recreate FFDM images for final interpretation, or
3. Transmit images to the patient or other medical institutions for final interpretation.

(3) 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 over-reading cannot be used toward initial or continuing experience requirements.

(4) 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.

e. **Digital Mammography Image Acquisition System Upgrades.** In the event that equipment is upgraded (same manufacturer) or the manufacturer changed, the existing images must be backed up for retention purposes, and an acceptable method of accessing the images must be available. *NOTE: 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 a hardcopy film of interpretation quality created for them. The program may not charge for creating the first hardcopy version of the mammogram. However, if the patient requests additional hard copies of the mammogram, the program may pass the costs of the additional hardcopies on to the patient, in accordance with release of information policies and guidance.

g. **Image Archiving.** Periodic, and not less than monthly, validation of active image archiving to both the primary PACS long-term storage and back-up storage (e.g., VistA Imaging, mirror, or removable media, etc.) must be documented and retained by the Mammography Program in a secure area. Documentation must consist of (written) steps taken to validate the archival process and the notation of the archiving validation (e.g., in the form of a log with initials, etc.). The documentation must be available for transmission to the VHAMO, or National Radiology Program Director, upon request.

29. OUTSOURCED MAMMOGRAPHY

a. **Outsourced Mammography Providers.**

(1) All VHA facilities referring patients off-site for mammography (to an affiliate, under contract, sharing agreement, fee for service, another VA, etc.) must ensure the off-site facility is either currently:

- (a) FDA-certified,
- (b) (FDA-approved) State-certified under MQSA, or
- (c) VHA-certified to perform mammography.

(2) A valid and current VHA certificate posted in a VHA facility, an FDA certificate posted in a non-VA facility, or the program being listed on the FDA mammography website is assurance that the facility is appropriately accredited and certified to perform mammography.

(3) The FDA Locator for (non-VA) certified mammography facilities can be used to validate current certification status and can be found at:

<http://www.fda.gov/CDRH/MAMMOGRAPHY/certified.html>

b. **Contract Providers.** Contracts and agreements must include written language that the contractor remains accredited with an FDA-approved (mammography) AB and must remain certified with the FDA or an FDA-approved (mammography) certifier. Only certified providers may supply services to authorized VA beneficiaries. Failure to retain accreditation or certification must be communicated to the facility A&MMS contracting officer or Contracting Officer's Technical Representative (COTR) immediately.

(1) Contracts, agreements, etc., with non-VA facilities to provide stereotactic breast interventional procedures (e.g., breast biopsy) must be in writing (see App. C).

(2) The off-site non-VA mammography facility has the same legal obligation to communicate the results of the exam to the patient and to the ordering practitioner that VHA Mammography Programs have, which includes the following:

(a) **To Patients.** There must be a written lay summary within 30 days, if the final assessment is "Suspicious" or a communication of results within 5 working days if the final assessment is "Highly Suggestive of Malignancy."

(b) **To Ordering VHA Practitioner.** There must be a written report within 30 days of the procedure, if the final assessment is "Suspicious." If the final assessment is "Highly Suggestive of Malignancy," communication of the report must be within 3 working days.

(c) Since the site performing the mammogram is required to communicate the results directly to the patient, there is no additional requirement for the referring VHA health care facility to also provide a written communication directly to the patient, unless local facility policy requires one. However, if additional follow-up, treatment or care of the Veteran is recommended, it is the responsibility of the ordering VHA practitioner to attempt to contact the patient, continue the appropriate treatment regimen, and maintain the continuity of care.

(3) Patient reports must be incorporated into VistA, e.g., through dictation into VistA, if possible, or at the very least VistA Imaging. **NOTE:** *Software modifications allow for easier integration of outside (contracted or fee basis) radiology and nuclear medicine reports into VistA. This outside reporting integration allows more accurate inclusion of information into the electronic medical record and allows medical alerts, radiology workload capture, clinical reporting, ordering, and patient care tracking.* In the absence of software enhancements, scanning a copy of the paper report into VistA Imaging and associating it with an order for an outside radiology procedure is required.

(4) It is the external radiologist's responsibility to make any positive findings known to the patient. However, it remains the responsibility of the ordering VHA practitioner to discuss the meaning of the findings and the alternatives for further study, treatment, or referral with the patient. **NOTE:** *See Appendix B for a list of elements that need to be considered for inclusion in any outsourced mammography agreement or contract.*

c. **Fee Basis Providers.** Veterans are to be encouraged to use only certified providers, and to execute a Release of Information to provide VHA with a copy of the report, images, etc.

30. REFERENCES

- a. Pub. L. 102-539, Mammography Quality Standards Act of 1992.
- b. Pub. L. 104-262, Veterans' Health Care Eligibility Reform Act of 1996.
- c. Pub. L. 105-114, Veterans' Benefits Act of 1997.
- d. Pub. L. 105-248, Mammography Quality Standards Reauthorization Act of 1998.
- e. ACR Practice Guideline for Communication of Diagnostic Imaging Findings
- f. VA Directive 6212, Security of External Electronic Connections.
- h. VHA Handbook 1004.01.
- i. The Food and Drug Administration (FDA) regulations, Title 21 Code of Federal Regulations (CFR) Part 900.
- j. ACR Practice Guideline for the Performance of Screening and Diagnostic Mammography.
- k. ACR Practice Guideline for the Performance of Contrast- Enhanced Magnetic Resonance Imaging (MRI) of the Breast.
- l. ACR Practice Guideline for the Performance of Stereotactically Guided Breast Interventional Procedures.
- m. ACR Mammography web site: <http://www.acr.org/accreditation/mammography.aspx>

n. FDA Locator for a non-VHA certified mammography facilities:
<http://www.fda.gov/CDRH/MAMMOGRAPHY/certified.html>

o. FDA website for MQSA policy guidance:
<http://www.fda.gov/CDRH/MAMMOGRAPHY/robohelp/START.HTM>

p. U.S. Preventive Services Task Force (USPSTF), Agency for Health Care Research and Quality, at: <http://www.ahrq.gov/clinic/uspstf/uspsbrca.htm>

q. VHA Directive 1663, Healthcare Resources Contracting

**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 Diagnostic Code
Negative	<i>Negative</i>	BI-RADS 1	1101
	Negative Mammogram		
Benign	<i>Benign</i>	BI-RADS 2	1102
	Benign Finding		
	Benign Findings		
	Benign Abnormality		
	Benign Abnormalities		
	Benign Mammogram		
Probably Benign	<i>Probably Benign</i>	BI-RADS 3	1103
	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		
	Probably Benign Mammogram		
Suspicious	<i>Suspicious</i>	BI-RADS 4	1104
	Suspicious Finding		
	Suspicious Findings		
	Suspicious Abnormality		
	Suspicious Abnormalities		
	Suspicious for Malignancy		
	Suspicious of Malignancy		
	Suspicious Abnormality - Biopsy Should Be Considered		
	Suspicious Finding - 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 Cancer	
	Known Malignancy	
	Known Cancer	
Incomplete: Need Additional Imaging Evaluation	<i>Incomplete: Need Additional Imaging Evaluation</i>	BI-RADS 0 1100
	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 assessment category)	
	Incomplete Mammogram: Need Additional Imaging Evaluation	

ACCREDITATION

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

ELEMENTS TO BE ADDRESSED IN A MAMMOGRAPHY AGREEMENT OR CONTRACT

1. Successful outsourced procedure management requires the coordinated efforts of many people, including physicians, nurses, clerks and administrative staff working in the local community and the referring Veterans Health Administration (VHA) site. Outsourced procedures also involve complex technology, including electronic medical records, Picture Archiving and Communications Systems (PACS), computer networks, image processors, FAX machines, firewalls, authorized access, etc. All of these elements must work in coordination. All too often, contractual agreements are less than successful because of differing expectations for responsibilities, unrealistic performance requirements, or an inadequate plan for communication. These problems may be avoided by creating a well-written agreement for any outsourced procedure.
2. The goals of coordinated care need to be clearly stated. A workflow process must be defined, listing each step of the process. Procedures and responsibilities need to be specified in detail. All persons involved need to understand and agree to their responsibilities. **NOTE:** *It may be helpful to name a mammography or outsourced procedure coordinator who maintains records, patient tracking, follow-up, and is the point of contact for reporting problems.*
3. Depending upon the scope of the mammography plan, agreement, or contract, the following is a listing of points to be considered for inclusion. This list attempts to include many of the important points for consideration, but it is not exhaustive:
 - a. Dates, days of week, and hours of day of service.
 - b. Types of studies, and the expected volume.
 - c. Names of mammography interpreting physicians, proof of active mammography accreditation and certification, which distinguishes the facility providing services or procedures as Mammography Quality Standards Act 'MQSA' certified.
<http://www.fda.gov/CDRH/MAMMOGRAPHY/certified.html>. It must be a requirement that the contractor is not to substitute other mammography interpreting physicians for the privileged ones named in contract without verification of qualifications.
 - d. Performance metrics are important in medical processes where speed and accuracy are vitally important. Expectations for turnaround time, and performance penalties, need to be predetermined.
 - e. Patient satisfaction and patient care outcomes also need to be measured and evaluated as part of whether the contract or the agreement is successful.
 - f. Performance time needs to be monitored for notifications, reports, and report verification, as relevant to the types of studies to be read. How will timeliness be monitored? Policy for

communication of results and for direct communication of urgent results, as applicable to the scope of contract, must be established.

g. Standards for accuracy, completeness of reporting and how amended reports will be handled must be established.

h. When there is no in-house mammography at the requesting site, how will the outsourced provider be notified that a procedure must be done? How may procedure modifications to the requested study be authorized or amended? Depending on the types of studies specified in the contract, how are patients to be evaluated prior to procedure, and how will written informed consent, if necessary, be obtained?

i. How will the reason for study (history) and other medical information be provided to the outsourced mammography facility? Who selects prior comparison studies, which may be under VHA control; how will they be selected and how will they be sent to the local outsourced provider? If additional or adjunct prior studies are required, who should the outsourced mammography site contact, and to whom they should be sent?

j. How are referring clinicians to discuss the appropriate ordering of studies with the local mammography provider, if relevant to the nature of the contracted service? How is the outsource mammography site to contact the VHA ordering practitioner to clarify the reason for study? How is the ordering practitioner to be notified of an urgent finding, and how will this will be documented? If the ordering practitioner cannot be contacted, what fallback plan is available for the communication of emergent results? How are ordering practitioners to contact the local provider to find results or clarify interpretations?

k. How will reports be created, communicated, and by whom? How will the report text be up-loaded into the Veterans Information System and Technology Application (VistA)? How will the outsource mammography provider verify reports if it will be directly (electronically) entered into VistA. How will protected patient information be secured?

13. How will the requesting facility record the names of patients and time that each procedure was requested, films or images sent, and names of reports received?

14. How will the names of responsible individuals and contact numbers be kept current? How will sudden changes in assigned personnel or contact numbers be communicated?

15. How will the QA (QA) process by which deficiencies in timeliness and report accuracy are noted, be corrected?

16. A robust tracking system must be in place to perform QA, discover missing reports, calculate workload and billing, assess penalties, defend VA in the event of a tort claim, and adjudicate disputes. Activity records need to be trended. Records need to be reconciled with the contractor frequently.

17. Does the contractor agree to participate in claims defense?

18. How will parties be notified if the local provider must cancel or defer the patient's appointment?
19. Where will reports be stored? Where will study films and images be archived?
20. Telemammography may be utilized as long as national Federal mammography requirements, security, privacy, and VA and VHA standards are met and maintained. Who will provide telemammography and network equipment? If contractor provides equipment, what are the minimum standard requirements? Only lossless compression schemes are approved for mammography.
21. Are VA security directives, including secure firewalls, isolation of networks, security and privacy training, and rules of behavior applicable and are they defined. Is there a method of secure electronic transmission? Is there use of an approved gateway, such as 1VA Virtual Private Network (VPN)? Is there compliance with access rules, including authorization and logging of audit trail? Who has the responsibility for timely application of security patches to operating systems, firewall, and antiviral software? Is there a requirement for a Health Insurance Portability and Accountability Act (HIPAA) Business Associate Agreement (BAA)?
22. Is there a requirement for pre-award inspection of contractor's facility?
23. There needs to be a provision for periodic meetings to review workload, coding, performance metrics, and resolving problems.
24. Infrastructure and technical support is desirable to initiate and facilitate needed medical record entries.
25. There must be some contingency plan and tracking for failure of equipment, absence of personnel, and patient education.
26. At a minimum, the following transactions must be recorded for each study:
 - a. Patient requisitions and films/images sent, time, and by whom.
 - b. Patient reports received: patient identifying information, name of outsourced provider, procedure(s) authorized/performed, name of interpreting physician, date received, and received by whom.
 - c. Time/date of report verification.
 - d. Conversations between the interpreting physician(s) and treating team regarding emergent results must be documented in the report.
27. There must be a provision for periodic meetings to review workload, coding, performance metrics, and resolving problems.

28. The appropriate BI-RADS code must be included in the report together with the FDA mandatory final assessment category wording.

29. If the ‘outside’ radiologist has access to VistA or uses the radiology service dictation system they may enter their reports in the Radiology Package of VistA. If reports are received by the VA medical center as hardcopy, they will be scanned into VistA Imaging and linked to an administrative report in VistA. 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 assessment category must be entered according to the table in Appendix A.