

## MAMMOGRAPHY STANDARDS

- 1. REASON FOR ISSUE:** This Veterans Health Administration (VHA) Handbook is issued to provide procedures for the administration, accreditation, certification and conduct of mammography in Department of Veterans Affairs (VA) facilities as required by Public Law 104-262.
- 2. SUMMARY OF CONTENTS:** This VHA Handbook contains implementation instructions and procedures for the application of mammography quality standards, and accreditation and certification of mammography units in VA facilities or those managed by VA facilities.
- 3. RELATED ISSUES:** VHA Directive 1104 (to be published).
- 4. RESPONSIBLE OFFICE:** The Office of Patient Care Services, Diagnostic Services Strategic Healthcare Group (SHG) (11/115), is responsible for the contents of this VHA Handbook. Questions may be referred to the VHA Mammography Office (VHAMO) at (919) 286-0411, extension 1 5155. FAX communications may be sent to (919) 286-6831.
- 5. RESCISSIONS:** VHA Circular 10-91-101, and VHA Directive 10-95-066, are rescinded.
- 6. RE-CERTIFICATION:** This VHA Handbook is scheduled for re-certification on or before the last working day of August 2008.

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Under Secretary for Health

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**CONTENTS**

**MAMMOGRAPHY STANDARDS**

<b>PARAGRAPH</b>	<b>PAGE</b>
1. Purpose .....	1
2. Background .....	1
3. Scope .....	2
4. Function of Mammography .....	4
5. Accreditation, Certification and Evaluation .....	6
6. Alternative Standards .....	15
7. Personnel Standards .....	16
8. Quality Assurance .....	17
9. Additional Mammography Review (AMR) .....	23
10. Interventional Stereotactic Breast Procedures .....	25

## MAMMOGRAPHY STANDARDS

### 1. PURPOSE

This Veterans Health Administration (VHA) Handbook is issued to provide procedures for the administration, accreditation, certification and conduct of mammography in Department of Veterans Affairs (VA) facilities as required by Public Law 104-262.

### 2. BACKGROUND

a. Public Law 98-160, the Veterans Health Care Amendments, was landmark legislation mandating VA to provide 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, i.e., mammography.

b. On October 27, 1992, Congress passed Public Law 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 local mammography facilities were included under the law except those of 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 continue to perform mammography. The Food and Drug Administration (FDA) within the Department of Health and Human Services (HHS) published implementing regulations for the MQSA, Title 21 Code of Federal Regulations (CFR) Part 900.

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

d. In 1996, the Congress reaffirmed the Under Secretary for Health's decision by including VA facilities within the application of the law through passage of Public Law 104-262, the Veterans' Health Care Eligibility Reform Act (38 U.S.C. 7319), Section 321. This law stated the Secretary, VA, in consultation with the Secretary, HHS, must publish mammography regulations to include:

(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) Quality assurance and quality control 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 facilities used by and in VA health care facilities will be provided. 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: This, in essence, requires VA mammography facilities to meet the basic requirements of MQSA, but left the enforcement and oversight of VA's on-site mammography facilities to VA.*

e. The Veterans' Benefits Act of 1997 (Pub. L. 105-114), enacted November 23, 1997, requires the VA Under Secretary for Health to develop a national policy for VA on mammography screening for veterans. The law states that it is the sense of Congress that VA 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.

g. The mammography regulations (21 CFR Parts 16 and 900) have been and continue to be modified over time. Rather than revising and publishing VA regulations so that they are equal to, or more stringent than 21 CFR Parts 16 and 900, this Handbook substitutes 21 CFR Parts 16 and 900 for VA regulations.

### 3. SCOPE

a. Radiology Service provides the principal medical diagnostic and therapeutic radiological services in all VA medical centers and sets the standards for quality and radiographic procedures for patient care in the medical center. In breast radiography, and in all mammography, the effectiveness and success of screening, depends on the consistent production of high-resolution, high-contrast mammographic images.

b. A distinct sub-section of system wide Radiology Services have committed their resources and expertise to performing mammography. They have been granted the recognition and authority to perform this important screening and diagnostic procedure on-site. All other VA medical facilities must use certified off-site providers.

c. All breast radiography performed within VA for the diagnosis and/or detection of breast cancer must meet the requirements of 21 CFR Parts 16 and 900 (MQSA). At such point in time that Federal regulations are promulgated concerning interventional, digital, and/or other mammographic modalities, those regulations must apply to VA facilities authorized to perform mammography.

d. All VA mammography facilities must achieve accreditation prior to being offered certification by VA to perform mammography. Accreditation must be on-going and successfully maintained. The applicable requirements of 21 CFR Parts 16 and 900, and of an appropriate

private non-profit accrediting body (AB) must be met prior to any mammography patient care services being offered.

e. All on-site VA mammography facilities must be certified by VA prior to performing mammography and must maintain certification to continue to provide mammography.

f. All VA facilities referring patients off-site for breast radiography (to an affiliate, under contract, sharing agreement, fee for service, another VA, etc.) must ensure the off-site facility is either currently FDA-certified (FDA-approved), State-certified under MQSA, or VA-certified to perform mammography. All agreements, contracts, etc., to obtain off-site (non-VA) mammography services must be in writing and contain such language to ensure the mammography site will only provide services to authorized VA beneficiaries as long as its certification is maintained. Contracts, agreements, etc., with non-VA facilities to provide stereotactic breast interventional procedures (e.g., breast biopsy) must be in writing and acknowledge that these procedures are to be performed in accordance with the American College of Radiology (ACR) standards and guidelines. Contracts, sharing agreements, etc., with non-VA facilities must describe processes to ensure the:

- (1) Coordination of care, and
- (2) Provision of VA required data for reporting, to include:
  - (a) Timeliness of patient communications;
  - (b) Study results;
  - (c) Patient demographics; and
  - (d) Quality and performance statistics (e.g., patient satisfaction and outcomes).

g. All mammography performed on-site under VA auspices, regardless of location, must undergo an annual mammography standards inspection to assess whether or not the mammography program is meeting the requirements of 21 CFR Parts 16 and 900. **NOTE:** *Federal inspectors must perform these inspections.*

h. An annual mammography facility physics survey, consultation, and evaluation by a qualified medical physicist under the provisions of 21 CFR Parts 16 and 900, must be performed at each VA mammography site, and the results reported to the facility director so that corrective action(s), if needed, may be taken to ensure mammography standards and safety.

#### 4. FUNCTION OF MAMMOGRAPHY

a. The principles of quality for 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 of data for outcomes of the mammography services.

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

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

d. Breast interventional procedures using stereotactic needle targeting equipment to ensure that patients receive optimum tissue sampling with the lowest possible risk, 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) biopsy.

e. **Management and Trend Analysis**

(1) All certified mammography units are responsible for proper utilization and confidentiality of Veterans Health Information Systems and Technology Architecture (VistA) data collection and management systems, and may include the Women's Health Software (WHS) and the Computerized Patient Record System (CPRS). VA-certified sites must ensure that mammography results and related pathology results are entered into approved software; e.g., WHS, VistA and/or CPRS.

(2) Diagnostic Services (Radiology and/or Laboratory) and the Women Veterans Health Program share a joint responsibility for tracking results of mammography and/or pathology procedures on women performed off-site, and ensuring the data is captured and entered into approved software; e.g., WHS, VistA and/or CPRS.

(3) Data submitted as a result of inspections, evaluations, and surveys to VA, are reviewed by the VHA Mammography Office (VHAMO), trended and analyzed for reporting to Congress, VA Central Office, Veterans Integrated Service Networks (VISNs), and medical facility management.

**f. Qualifications, Responsibilities, and Role of Mammography Staff**

(1) The Chief, Radiology Service is responsible for the overall direction and coordination of the functions of the mammography unit based on the mission, special needs, and size of the facility. The functions of this position are diverse and encompass patient care, administration, education, and research.

(2) Medical care responsibilities may only be delegated to qualified physicians; technical responsibilities may be delegated to other qualified staff. The Chief, Radiology Service, however, remains responsible for the overall operation and administration of the mammography unit to ensure that quality patient services are provided, and that personnel operations and unit management run smoothly and efficiently.

(3) The Chief Radiology Service is responsible for clearly designating, in writing, the following:

(a) A lead-interpreting physician to oversee the mammography program. No other individual can be assigned or retain the responsibility for quality assurance tasks unless the lead-interpreting physician has determined that the individual's qualifications for, and performance of, the assignment are adequate.

(b) The lead-interpreting physician is responsible for ensuring that a facility's mammography quality assurance (QA) Program and medical audit are established and meet stated requirements. Lead-interpreting physician means a licensed physician who interprets mammograms and who meets the requirements set forth in 21 CFR 900.12(a)(1).

(c) Interpreting Physicians. The physicians who interpret mammograms provide consultation to referring clinicians regarding the medical significance of those clinical images. They must assume responsibility for the quality of mammography and for implementing an effective QA Program at their site. Interpreting physician means a licensed physician who interprets mammograms and who meets the requirements set forth in 21 CFR 900.12(a)(1). All interpreting physicians interpreting mammograms for the facility must follow the facility procedures for corrective action when the images they are asked to interpret are of poor quality. In addition, the interpreting physicians must participate in the facility's medical outcomes audit program.

(d) Quality Control (QC) Technologist. A QC technologist must be assigned responsibility for all individual tasks within the QA Program not assigned to the lead-interpreting physician or the medical physicist. The tasks are to be performed by the QC technologist or by other personnel qualified to perform the tasks. When other personnel are utilized for these tasks, the QC technologist must ensure that the tasks are completed to meet the requirements of 21 CFR 900.12(a)(2) and 12(e).

(e) Mammography Radiologic Technologist. The mammography radiologic technologist's general responsibilities center on patient care and image quality. More specifically, these responsibilities include patient positioning, compression, image production, film processing,

infection control, and QC. This individual must have specific training in the use of radiographic equipment and the positioning of patients for radiographic examinations; in addition this individual must meet the requirements set forth in 21 CFR 900.12(a)(2) in order to perform mammographic evaluations.

(f) **Medical Physicist.** A designated qualified medical physicist's services are required to survey mammography equipment and oversee the equipment-related QA practices of the facility.

(g) The medical physicist is responsible for performing the facility's annual survey (which includes all the annual QC tests specified in 21 CFR 900.12(e)(5), the phantom image quality test, other (new) mammographic modality tests, as well as evaluation of the QC tests and results that are normally conducted by the QC technologist), and providing the facility with a report of the annual survey. The medical physicist is also responsible for 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)(10). The medical physicist must be trained in evaluating the performance of mammography equipment, the facility QA Programs, and must meet the qualifications for a medical physicist set forth in 21 CFR 900.12(a)(3).

(h) Facility specific policies and procedures for mammography infection control, consumer complaints, medical audit, medical report content, patients with breast implants, direct communication of results to patients, and QA and/or QC issues must be developed in writing and be in accordance with the provisions contained in 21 CFR 900.

g. **Off-Site (Non-VA) Mammography.** All VA medical facilities referring patients, under any circumstances, to outside (non-VA) mammography facilities must verify that the site(s) has a current and valid mammography MQSA certificate, issued by either FDA or an FDA-approved State. The retention of an FDA certificate is assurance the facility is appropriately accredited and certified to perform mammography. No patients can be referred to a mammography facility that is not FDA\* or VA-certified. VA facilities executing sharing or contractual agreements need to consider inclusion of appropriate language in those documents.

*\*Some States may qualify as (non-VA) mammography certifiers if approved by FDA.*

## 5. ACCREDITATION, CERTIFICATION, AND EVALUATION

a. **Scope.** A mammogram may not be performed at a VA facility unless that facility is accredited for that purpose. Any VA medical facility interested in performing mammography on-site must apply for and attain accreditation from an approved non-profit AB that meets the requirements of 21 CFR 900, Sections 900.3 and 900.4, and 38 U.S.C. 7319(a). VA on-site mammography facilities cannot use FDA-approved States as accreditation bodies or certifiers.

b. **Submission of Findings.** On a periodic basis, FDA and ACR must submit the findings of their evaluative processes to VA and to the individual facilities.

c. **Identification of Contact Personnel.** For evaluations performed under the VA Mammography Program, the contact personnel are as follows:

(1) **Chief Radiology Service.**

(a) The Chief Radiology Service, or designee, is considered the facility contact person for receipt of, and the intra-facility distribution point for, general mammography information and guidance issues.

(b) The Chief Radiology Service of each on-site mammography unit is considered the “responsible person for (mammography) compliance.” In this capacity the Chief receives correspondence concerning mammography evaluation results.

(2) **Chief Executive Officer.** The Chief Executive Officer is considered to be the highest-ranking official for facility management issues.

(3) **VISN Director and Medical Facility Director.** The offices of the respective VISN Director and medical facility Director, or Chief Executive Officer, also receive notification of accreditation and certification status changes, and evaluation results.

d. **Accreditation and Certification.** Accreditation of a facility is necessary as a precursor to certification. If a facility is not accredited it cannot be certified, in which case, it cannot legitimately perform mammography. On the other hand, a facility may apply for and achieve accreditation by an approved AB however, VA may, based on other internal information, choose not to certify the facility to perform mammography. In this case, the facility is accredited, but not certified, and without certification it cannot legitimately perform mammography.

e. **Accreditation and Certification Phases**

(1) **Provisional.** An initial application acceptable to the AB qualifies for an interim period of accreditation. The AB notifies VA, which may issue a 6-month temporary (provisional) certificate to the facility. This certificate allows the facility to operate for up to 6 months while attempting to achieve fully-certified status.

(2) **Ninety-Day Extension.** A one-time extension may be granted to facilities that are provisionally certified. In order to qualify for the extension, the facility must provide documentation in a format acceptable to VA stating its plan to complete the certification process on time. The AB must be consulted and may recommend granting the extension. After review of the facility’s request and the AB’s recommendation, VA may authorize the 90-day certificate extension.

(3) **Full Certification.** When all stages of the evaluation are completed, a final report that includes specific assessments and recommendations is issued. The AB awards accreditation to those facilities successfully meeting all of the criteria for each approved mammography unit. The AB notifies VA so that a full 3-year certificate may be issued if VA determines that the facility should be authorized to perform mammography on-site.

(4) **Annual Update.** The AB requires each fully accredited mammography facility to annually update basic information. The AB specifies the format and content of the required information.

(5) **Renewal.** Eight months prior to the end of each 3-year full-accreditation period, mammography facilities are provided the opportunity to apply to the AB for an additional 3-year period of accreditation.

(6) **Accreditation Denial.** The AB can, and is expected to, take action to revoke or suspend the accreditation of facilities that do not comply with established standards. Facilities may appeal denial of accreditation directly with the AB.

(7) **Re-Instatement.** Re-instatement is the appropriate procedure for re-opening a facility's mammography unit whose certification has lapsed, where there is insufficient time to repeat a test after a first deficiency, or after accreditation failure. VA may permit a previously certified facility that has allowed its certificate to expire, that has been refused a renewal of its certificate, or that has had its certificate suspended or revoked, to apply to have their certificate re-instated. The facility needs to apply to the AB for re-instatement after correcting any deficiencies. Normally reinstatement is encouraged as long as the facility demonstrates its intent and ability to produce quality images and practice high-quality mammography.

(8) **Interim Notice Memorandum.** VA may issue an interim notice memorandum to a mammography facility when there is a delay in issuing or delivering a certificate to a facility that has met the requirements for a provisional or re-instatement certificate, or has completed accreditation or renewal and the facility's certificate has or is about to expire. The interim notice memorandum may be sent to the facility by facsimile or electronic mail.

f. **Certification Denial.** Although VA relies substantially on the AB's determinations in making decisions about whether to issue certificates, there may be situations where VA has additional information not available to the AB, e.g., FDA inspection results, or when VA has reason to disagree with the AB's evaluation (accreditation) of the facility's ability to perform quality mammography. In those circumstances, VA retains discretion to deny certification, even if the facility has become accredited.

g. **Submission of Accreditation Materials.**

(1) Accreditation materials need to be submitted in a prompt and timely manner to allow the review process to be completed prior to certificate expiration, which would mean an interruption in mammography service delivery.

(a) The AB requires the submission of:

1. A thermoluminescent dosimeter (TLD);
2. Clinical images;

3. An image of a specially designed breast phantom and processor quality control data;
4. Personnel credentials; and
5. The medical physicist's survey from any facility that attempts to apply, re-instate, or renew.

(b) The first three accreditation materials are required to be submitted from the same 30-day period.

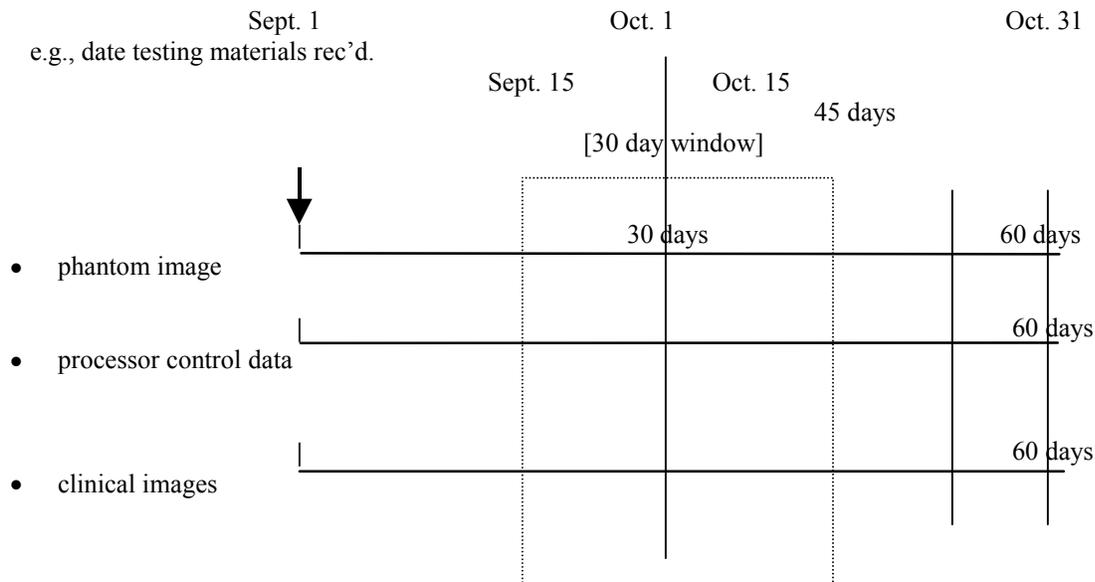
(2) Some facilities with lower patient volumes may experience difficulty in submitting their 'best' clinical images with strict adherence to the 30-day time frame. The descriptor "best" refers to positioning and image quality as well as a 'negative' overall mammography report interpretation assessment category. If the facility's best image turns out to contain cyst(s), lump(s), bump(s), etc., but the interpretation is negative, a copy of the interpreting radiologist's report (deleting patient identifying information) needs to be submitted with the clinical images. This shows the AB clinical image reviewers that although the image contains minor benign anomalies, the interpreting physician is cognizant of the additional mammographic features on the image and has interpreted the film as "benign," e.g., no evidence of malignancy - overall mammography report interpretation assessment category. The films submitted to ACR are to be selected from those that are obtained while routinely performing mammograms during the regular course of business. It is an unacceptable practice; legally, ethically, and morally to expose any patient repeatedly to obtain images for the image review. In absolutely no case is a patient to be repetitively exposed or be subjected to additional unnecessary mammograms to provide the clinical images for accreditation.

(a) Discussions with ACR staff indicate that facilities with lower mammography volume sometimes experience difficulties in submitting their sample images in a timely manner for accreditation and/or renewal clinical image review. There is some flexibility for facilities having difficulty obtaining examples of their best clinical images obtained during their regular course of business (performing mammography).

(b) The mammography facility has 45 days in which to capture a month (30 days) of activity. The facility needs to submit the phantom image and the clinical images promptly to ensure there is sufficient time for review, and if needed, re-submission of the failed images. ACR automatically generates a letter 45 days after the accreditation application is sent to the facility, indicating that the phantom and clinical images are overdue. ACR expects the images submitted to be original images not copies. It is also requested that only clinical images that are "negative" be submitted for evaluation. **NOTE:** *On rare occasions, "benign" images may be submitted, however, it is necessary to contact VHAMO before doing so.* These films need to be examples of the facility's best images.

(c) Traditionally, VA mammography sites do not experience large mammography volumes. Any VA facility needing an extension up to an inclusive total of 60 days in which to obtain examples of the best work (clinical images) for submission to ACR because of a low volume mammography program must contact VHAMO.

(d) This is how the process works. The phantom image, processor control data, and clinical images will need to continue to be within the same relative period. See the following diagram.



1. Standard example: If the test materials are received on September 1, in theory, one has until October 15, (45days) to record the month of processor QC, which consists of at least 20 data points, make the phantom exposure, obtain clinical images and return them to ACR before the end of the 45 day limit.

2. Extension example: The test materials are received on September 1. The processor QC is recorded as indicated, but the mammogram volume does not allow for sufficient number of patients to permit a best work example of a fatty and/or dense breast. If by September 30, there are no good examples of work to be submitted, and more time is needed, call the VHAMO and ask for an extension. For example, on October 16 and 20 good clinical examples are obtained, and the phantom image exposure is obtained on October 21. Then there is:

a. Processor QC from Sept 1 through October 21, which has at least 20 data points, clinical images taken October 16 and 20, and a phantom image taken October 21.

b. The phantom and clinical images need to have been taken within 30 days of each other; at least one month of QC and at least twenty data points would have been accomplished in 51 days.

h. External Proficiency Assessments. To ensure reliability of clinical images in the mammography program and to maintain certification, each mammography unit must undergo accreditation evaluation, Federal compliance testing, and a medical physics survey.

**(1) Accrediting Body Evaluations**

(a) Accreditation offers interpreting physicians the opportunity for peer review and evaluation of their facility's staff qualifications, equipment, QC and QA programs, image quality,

breast dose, and processor QC. The requirements used by an AB to accredit a mammography facility are contained within the final rules, 21 CFR 900.3 and 21 CFR 900.4.

(b) During the course of a year, the AB is required to conduct onsite visits and random clinical image reviews of a sample of the facilities it accredits in order to monitor and assess facility compliance with mammography standards. The criterion established by the AB for these assessments is in addition to the annual accreditation update and triennial renewal process.

(c) For those facilities that do not meet the criteria, the AB makes specific recommendations for improvement. These recommendations provide the necessary guidance so that a facility can meet the criteria after corrective action, and make a re-application, if necessary. Deficiencies can result in one or more of the following areas: staff qualifications, equipment, QC and QA programs, image quality, breast dose, and processor QC.

1. **First Deficiency.** The facility may appeal the deficiency; may resubmit items that failed for further review (presuming sufficient time remains on the certificate to allow for the review to be completed); may withdraw from performing mammography; or request reinstatement.

2. **Second Consecutive Deficiency.** The facility must cease mammography upon a second deficiency notification; however, it may appeal, request reinstatement, or withdraw from performing mammography. The facility must submit a corrective action plan (CAP) acceptable to the AB before the facility can be reinstated. If approved by VA, the facility is treated as a new facility, and issued a provisional (6 month) certificate. All the application criteria and information must be completed in a satisfactory manner to obtain a 3-year accreditation and certification.

3. **Third Consecutive Deficiency.** The facility must cease mammography upon a third deficiency notification; however, it may appeal, request reinstatement, or withdraw from performing mammography. The facility must submit a CAP acceptable to the AB before the facility can be reinstated. Additionally, the facility must submit to a scheduled on-site survey (SOSS) performed by the AB at the facility's expense. VA reviews the CAP and the results of the SOSS. If approved by VA, the facility is treated as a new facility, and issued a provisional (6 month) certificate. All the application criteria and information must be completed in a satisfactory manner to obtain a 3-year accreditation and certification.

## (2) Accreditation Appeal Procedures

(a) **Approved ABs.** Approved ABs perform a service and they provide VA/VHAMO with the VA facility results. These outcomes are the result of facility performance compared with nationally approved standards. VA/VHAMO considers certification of a mammography facility after accreditation by an approved private non-profit organization in accordance with 38 U.S.C. 7319 and 42 U.S.C. 262b. Accreditation determinations may be addressed directly with the AB. Appeals are initially processed by the AB after which the facility has the prerogative to request review by VHAMO, who retains final jurisdiction. ***NOTE:*** *Any questions concerning the continuance or cessation of the performance of mammography after an accreditation deficiency*

*and/or failure may either be addressed to the AB or VHAMO for additional guidance or clarification.*

(b) Process

1. Initial appeals concerning accreditation failures need to be addressed directly to the AB in the format outlined within the accreditation deficiency letter sent to the facility by the AB.
2. Document, with photo copies (if possible) of the items and/or issues in question.
3. Send the appeal and accompanying documentation to the AB for initial review and comment. Should a facility wish an additional level of review after the AB has rendered a decision, all materials need to be sent for review to the VHAMO. The facility cannot perform mammography during the appeal, unless otherwise notified by VA. After review, facility management, including the Chief Executive Officer and the Chief, Radiology Service, will receive a reply in writing, affirming or removing the accreditation denial. The AB will also be apprised of the outcome of VA's decision.

(c) FDA Inspections

1. VA has entered into an Interagency Agreement (IAG) with FDA to utilize Federal mammography inspectors to conduct the mandatory annual mammography compliance inspections to meet the requirements of 38 U.S.C. 7319 and 42 U.S.C. 262b Sec. 354(g)(1). Mammography inspection results are reported to the individual facility and to VA for analysis, oversight, and enforcement.
2. Mammography Inspections must cover the following areas:
  - a. Equipment performance (including image quality (phantom) and dose);
  - b. Technologist and physicist QC and/or QA tests, tasks, and records;
  - c. Medical audit and outcome analysis records;
  - d. Medical records (mammography reports and films); and
  - e. Personnel qualification records.
3. Findings are to be categorized into four levels: Level 1 (most critical) to Level 3 (least critical) and no findings (full compliance). At the conclusion of the inspection, a summary report (results notification) will be left with the facility and will include any variances or deviations from the standards, categorized as follows:
  - a. **Level 1 (L1).** L1 is the most serious. It indicates a failure to meet key requirements that may compromise the quality of mammography services performed at the facility. VHAMO closely reviews each L1 finding. The facility should prepare a response to VHAMO within 15

working days from the date of the inspection results notification, outlining the facility's CAP to resolve the L1 violation(s). The facility may be directed by VA to take additional actions such as removing equipment from use, recalling patients improperly exposed, re-reading mammograms, etc.

**b. Level 2 (L2).** In the absence of L1 findings, a L2 finding indicates that the facility meets all key requirements but fails to meet significant mammography quality items. An L2 finding requires a response from the facility to VHAMO (Address: 508 Fulton Street, Suite F 3216, Durham, NC 27705) within 30 days of the date of the facility inspection results notification regarding the necessary action(s) to correct the L2 violation(s).

**c. Level 3 (L3).** In the absence of L1 and L2 findings, L3 findings indicate that the facility meets all major requirements with minor exceptions. While the facility is expected to correct each violation found during the inspection as soon as possible regardless of its level, it is not required to send a written response to VHAMO concerning an L3 finding. Corrective actions regarding these will be checked during the next annual inspection.

**d. L1, L2 and/or L3 Violations.** Facilities must respond to any L1 and/or L2 violations in writing:

(1) L1 within 15 days after receipt of the L1 finding;

(2) L2 and repeated L3 findings, the facility must respond within 30 days after receiving inspection results.

(3) Non-repeated L3 findings do not need to be addressed in writing. However, these findings must be corrected and these corrections would normally be checked during the next annual inspection.

**e. Review of Findings.** All findings, especially L1 and repeat findings at L1 and L2, are reviewed by VA to determine whether additional corrective action or facility guidance is necessary to ensure national standards are attained and maintained.

**f. Inspection Appeal Procedures.** VA is responsible for overseeing the performance of its facilities, and for follow-up with the individual facilities to ensure that any needed corrective action(s) have been taken to remedy deficiencies. **NOTE:** *FDA is a contractor for VA performing a nationally mandated inspection service and provides VA with the results.*

**g. Process**

(1) Document, with photo copies (if possible), the items and/or issues the inspector cited. **NOTE:** *Consider in retrospect, it would be difficult if not impossible to recreate the environment, documentation, and other variables in place on the date of the inspection without proper documentation.*

(2) The request for reconsideration needs to be submitted through appropriate medical center channels and needs to include:

(a) A copy of the inspection findings and/or results report;

(b) A clear statement of the excepted issue(s);

(c) Reference(s) to any mammography standards, final mammography regulations, excerpts from guidance documents, etc., which support the facility's position; include copies of supporting documentation;

(d) 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.

(3) The memo and accompanying documents need to be sent to the VHAMO. Once it is reviewed, it may be forwarded to FDA for review and comment. The Chief Executive Officer and the Chief, Radiology Service, receive a reply in writing, affirming or removing the cited finding(s). VA must apprise FDA of the final outcome of the review.

**h. Medical Physics Surveys.** Once a year, usually every 12 months but not more than 14 months from the previous survey, each mammography unit must be surveyed by a qualified medical physicist or by someone in training under the medical physicist's direct supervision.

(1) The survey must include:

(a) Performance of the annual tests described in 21 CFR 900.12(e) and the QC tests for other modalities, as applicable;

(b) A review of the results of the QC tests conducted by the facility, as well as of written documentation of any corrective actions taken and their results;

(c) Any additional testing or consultation requested by the facility as part of the negotiated survey; and

(d) A report, which must be provided to the facility within 30 days of the date of the survey, that includes a summary of the areas tested and reviewed and recommendations for necessary improvements.

(2) 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 facility for which the annual survey is conducted need to be used whenever possible. For test procedures that determine dose to the average breast, the same kVp value (within +/- 1 kVp of that used clinically for the average breast) must be used for measuring both the entrance skin exposure and the Half-value Layer (HVL).

(3) The report must be dated and signed by (or contain the identification of) the medical physicist performing or supervising the survey and any other individual who performed or assisted in the survey. If the survey is done over a period of time, the dates of completion of the individual parts must be indicated in the report.

i. **Survey Appeal Procedures.** Issues with test performance, survey conduct, report content, etc., need to be directed to the local medical physicist, Acquisition and Materials Management Service (A&MMS), District Counsel, or the most appropriate individual to resolve the issue.

j. **Fees**

(1) Costs associated with the application for accreditation, reinstatement, renewal, AB on-site visits, random clinical image reviews, SOSS surveys, medical physicist surveys, and additional mammography reviews (AMR), if any, must be borne by the facility.

(2) Costs associated with the annual compliance inspections are centrally borne, through a national IAG between VA and FDA. Any additional or repeat facility visits due to inspection violations, etc., must be borne by the facility.

**6. ALTERNATIVE STANDARDS**

a. **Scope.** The proposed alternative standard must be as effective in ensuring quality mammography as the standard it proposes to replace; it must be in keeping with the purposes of 38 U.S.C. 7319 and 42 U.S.C. 263b.

b. **Processing Proposals**

(1) A proposed alternative standard needs to be developed following the guidelines found in 21 CFR 900.12(c) and submitted to the VHAMO, 508 Fulton Street, Suite F 3216, Durham, NC 27705, for review and assessment.

(2) When a request is received, a staff member(s) is assigned to review it to determine if it meets the criteria for approval. This individual(s) may also consult with experts in other parts of VA, FDA, the non-VA medical or scientific community, and with members of the National Mammography Advisory Committee. This review results in a recommendation to the Chief Consultant, Diagnostic Services SHG, or designee, that the request be accepted, rejected, or that more information be requested before a decision is made.

(3) VA may approve or deny, in whole or in part, a request for approval of an alternative standard, and must inform the applicant in writing of this action. The written notice must state the manner in which the requested alternative standard differs from the agency standard and a summary of the reasons for approval or denial of the request. If the request is approved, the written notice must also include 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.

## 7. PERSONNEL STANDARDS

a. **Scope.** Qualification requirements found in 21 CFR 900.12(a) apply to all personnel involved in any aspect of mammography, including the production, processing, and interpretation of mammograms and related QA activities.

(1) In order to independently interpret mammograms, one must qualify as an interpreting physician.

(2) In order to independently conduct surveys of mammography facilities and provide oversight of a facility's QA program, one must qualify as a medical physicist.

(3) In order to independently perform mammographic examinations, one must qualify as a radiologic technologist.

### b. **Personnel Standards and Re-qualification**

(1) **Chief, Radiology Service.** The Chief, Radiology Service must:

(a) Appoint a lead-interpreting physician who must meet all the requirements to be an approved interpreting physician and is assigned the general responsibility for ensuring that a facility's QA Program meets all of the requirements of 21 CFR 900.12(d) through (f).

(b) Appoint a QC technologist who must meet the mammography technologist requirements, and who is responsible for those QA responsibilities not assigned to the lead interpreting physician or to the medical physicist.

(c) Designate interpreting physician(s) and mammography technologist(s) who must meet and maintain the requirements of 21 CFR 900.12(a)(1) and (2), respectively.

(d) Be directly involved in the designation of a qualified medical physicist to annually survey the mammography equipment. The results of the survey must be reported to the Chief Radiology Service within 30 days of completing the survey. Because the duties of the medical physicist encompass more than just the annual physics survey, VA expects the facility to be able to call on the services of the qualified medical physicist throughout the year, as needed, to maintain the mammography system.

(2) **Other Personnel.** Other personnel who have not worked in mammography for a period of time after meeting the initial requirements must work under direct supervision when they return to mammography, if they do not meet the continuing experience or continuing education requirements. While under direct supervision, these personnel need to obtain the necessary continuing experience and Continuing Medical Education (CME) and/or Continuing Education Units (CEUs) to re-qualify before resuming independent work in mammography. A facility may be cited during an inspection if such personnel work without direct supervision prior to obtaining sufficient hours of CME and/or CEUs and continuing experience. Similarly, facilities need to ensure all new personnel meet all the appropriate requirements prior to permitting them to provide mammographic services independently. If these personnel are working independently and do not have the required credentials in continuing experience and CME and/or CEUs, the facility will be cited for these violations.

## 8. QUALITY ASSURANCE (QA)

a. **Purpose.** This paragraph provides direction and guidance in designing the mammography QA Program content in accordance with VA requirements: 21 CFR 1020.30, and 1020.31; 21 CFR 900.12(d) and (e); and Occupational Safety and Health Administration (OSHA)'s Blood Borne Pathogens Standard (29 CFR 1910.1030).

b. **Scope.** Each mammography facility must establish and maintain a QA Program to ensure the safety, reliability, patient's satisfaction, and accuracy of mammography services performed at the facility.

c. **QA Program.** Each mammography site must establish and implement a QA Program consisting of not less than the following elements:

(1) **Personnel Responsibilities.** Responsibility for the QA Program and for each of its elements must be assigned in writing to individuals who are qualified for their assignments and who are allowed adequate time to perform these duties.

(a) Prior preparation, rules compliance, and program diligence are keys to the successful establishment of a quality program which will pass any evaluation or inspection. It is strongly suggested that prior to mammography staff turnover and not less than quarterly, the QC and/or QA records need to be reviewed to ensure the continued existence, continuity, and completion meets subsequent inspection standards.

(b) The lead-interpreting physician, QC technologist, and medical physicist must ensure that records concerning employee qualifications to perform assigned QA tasks, mammography

technique and procedures, equipment QC (including monitoring data, problems detected by analysis of that data, corrective actions, and the effectiveness of the corrective actions), and safety are properly established, maintained, and updated.

(c) Whenever possible, the major routine data capture, tracking and analytical (QC and/or QA) automated systems must be able to be interfaced with the VA medical center VistA system. The requirement applies to contracted services provided as well.

(2) **Equipment and Assessment Methods.** All radiographic equipment used for mammography must be specifically designed for mammography in accordance with 21 CFR 1020.30, and 1020.31, and 21 CFR 900.12(b). Facilities are required to accredit all of their x-ray units used for mammography and have them certified by VHA.

(3) **Medical Physics and the Annual Survey.** Each facility must have the services of a qualified medical physicist available annually to survey mammography equipment and oversee the equipment-related QA practices of the mammography unit. At a minimum, the medical physicist(s) is responsible for performing the surveys and mammography equipment evaluations (see 21 CFR 900(e)).

#### (4) **Mammography Quality Control Testing**

(a) Mammography QC Testing must be performed at the frequencies noted in 21 CFR 900.12(e). Special attention is given to AB guidance manuals and other approved documents concerning testing methodologies. Required data must be recorded, tracked, and maintained in appropriate fashion. The mammography techniques and procedures used in conducting mammograms must be in written form and must be maintained until the next annual inspection that would verify compliance, or until an individual test has been performed two additional times at the required frequency, whichever is longer. Verifying compliance implies that if QC records for a given test were found to be deficient and the facility was cited during an annual inspection, these records must be kept until the facility corrects the problem.

(b) A facility must either have documentation from the chemical manufacturer, the supplier, or the film manufacturer showing that the processing chemicals being used provide results consistent with the film manufacturer's processing specifications, or the facility must establish that the film performance is sensitometrically equivalent to films developed according to the film manufacturer's specific recommendations. *NOTE: Facility personnel may wish to contact their medical physicist for additional advice and assistance with this issue.*

(5) **Patient Records Management.** Facility procedures must be developed and documented for preparing a written report of the results of each mammography examination performed under its certificate, consistent with 21 CFR 900.12(c) and its subsections. All mammography reports, regardless of where they are performed, must have the results entered into VistA. This includes all mammographic procedures performed on VA patients by non-VA mammography sites since the results will be used to guide patient care and treatment and must be electronically accessible, including but not limited to: timeliness of patient notification, study results and required follow-up. At the very minimum, mammography reports must be scanned into VistA and

administratively signed as verified. This administrative ‘verification’ attests to the correct entry of the report into VistA, that the report is for the patient for whom the procedure was ordered, and that the report is electronically released for access and use by the patient’s health care providers to treat that patient.

(a) Retention. VA Records Control Schedule (RCS) 10-1 contains the retention periods for mammography film. The Privacy Act and other internal VA documents, including RCS 10-1 provide direction and guidance concerning the retention of records.

(b) Mammography Report Content and Communication of Results. The Privacy Act regulations cover release of mammograms and patient medical information. The facility must release the original mammograms (films) and copies of the patient's reports to the patient or the patient’s designated representative upon receipt of a properly completed valid written request and/or consent. Many times (film) copies are of such poor quality that they do not provide adequate information. Sometimes only original films can provide the information that will prevent a patient from undergoing unnecessary invasive procedures, or to confirm the need for such procedures. The report must contain an overall final assessment of findings as consistent with 21 CFR 900.12(c).

1. Through the use of WHS and/or other suitable equivalent, each certified VA mammography site is required to establish a documented procedure to provide a summary of the written (mammography) report to the male or female mammography patient. The interpreting physician must document letters, reports, and/or verbal communication with the patient in the patient’s medical record according to MSQA standards and guidelines. The facility is expected to provide for the report’s entry into VistA, without regard to where the mammogram procedure was performed. The mammography report content must be communicated to the patient in terms easily understood by a layperson within 30 days from the date of the procedure. Documentation of letters and/or verbal communication with the patient must be entered into the medical record. If using the United States (U.S.) Postal Service, confirmation of the receipt of these results is not required.

2. When the mammography report assessment is “Suspicious” or, “Highly Suggestive of Malignancy,” the lay summary results and recommended course of action must be communicated as soon as possible. Communication to the patient of suspicious or highly suggestive results can ordinarily be accomplished within 5 working days. 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 written communication to the patient within 30 days of the date of the mammogram. The interpreting physician is to make reasonable attempts to ensure the referring provider is contacted with the mammography results. If the referring provider is not available, then a surrogate for the provider must be contacted with the results.

3. Any time the final mammography report is modified as a result of comparison studies or an addendum, an additional summary reflecting the final assessment category following these additional tests or comparison studies must be communicated. An addendum report must be provided to the referring physician and a lay communication provided directly to the patient.

4. If the referring physician and the mammography unit are located within the same VA facility, one written communication provided to the patient will meet the intent to notify the patient, if that is the facility's documented policy. Therefore, both the referring physician and the mammography unit will not need to each provide a separate written communication to the patient.

5. Mammographic images must be identified and/or labeled in accordance with the provisions of 21 CFR 900.12(c)5

6. VA facilities referring mammography off-site to an affiliate, whether under contract, sharing agreement, fee for service, etc., need to meet the following requirements:

a. The off-site mammography facility is expected to provide a written summary of the mammography report directly to the patient in terms easily understood by a layperson according to the provisions of MQSA. The interpreting physician must document letters, reports, and/or verbal communication with the patient in the patient's medical record according to MSQA standards and guidelines. Documentation of this communication must be available in the referring facility's VistA software or WHS package. When the mammography report assessment is "Suspicious" or "Highly Suggestive of Malignancy," the lay summary results and recommended course of action must be communicated as soon as possible. Communication of "Suspicious" or "Highly Suggestive of Malignancy" results to the patient can ordinarily be accomplished within 5 working days.

b. The off-site mammography facility needs to supply the referring VA facility with mammography reports of referred patients within 30 days of the date of the mammographic procedure. Communication of suspicious or highly suggestive results should ordinarily be sent to the referring VA facility physician within 3 working days.

***NOTE:** There is no requirement for the referring VA facility to also provide a written communication directly to the patient, unless local facility policy requires one. Direct verbal communication with the patient by the referring facility may be sufficient. Facilities referring patients for off-site mammography need to consider utilizing the WHS and/or other suitable equivalent to provide a written summary of the mammography report directly to the patient in terms easily understood by a layperson and communicate further health care related instructions and information.*

#### **(6) Infection Control and Facility Cleanliness**

(a) Facilities must 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 (see 21 CFR 900.12(d)(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, if any.*

(b) The facility must establish and follow adequate protocols for darkroom, screen, viewbox cleanliness, and viewing conditions. *NOTE: Examples of these may be found in AB guidance documents.*

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

2. Facilities where screen-film mammograms are interpreted or reviewed for comparison must provide both hot lights and masking devices to the interpreting physicians.

3. 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.*

4. If a separate viewbox is used by the QC technologist to check the density and quality of the mammography images, this viewbox needs to be similar to the reading viewbox in luminance and color of the light and it needs to be used with ambient lighting conditions similar to those in the room where the mammograms are interpreted.

(7) **Medical Audit.** A medical audit system must be established to collect and review outcome data for all mammograms performed consistent with 21 CFR 900.12(f).

(a) At a minimum, data collection needs to contain biopsy data on whether the tissue sample is benign or malignant. Additional information, such as staging and size of tumors, permits better evaluation of success in early detection of breast cancer. *NOTE: Reference to radiology journals or to the Agency for Health Care Policy and Research is suggested regarding recommendations for the collection of biopsy data.*

(b) At a minimum, the medical audit system must be able to document the following:

1. A definition of positive mammograms requiring follow-up;

2. A method to follow-up on positive mammograms;

3. A system to attempt to collect pathology results for all biopsies performed;

4. Methods to correlate pathology results with the final assessment category indicated by the interpreting physicians;

5. A method to include any cases of breast cancer among patients imaged at the facility that subsequently became known to the facility; and

6. A review of medical outcomes audit data for the aggregate of interpreting physicians, as well as each individual interpreting physician at least once every 12 months.

(8) **Breast Implants.** A written Standard Operating Procedure (SOP) sufficient to meet the requirements of 21 CFR 900.12(g) is required to ascertain which patients have breast implants, and to provide proper care to patients with breast implants prior to the performance of a mammogram.

(9) **Consumer Complaint Mechanism**

(a) The presence of an established written SOP containing the requirements of 21 CFR 900.12 (h) for collecting and resolving consumer complaints is required for compliance with mammography standards.

(b) A third party, e.g., a patient representative or patient advocate, may handle complaints for the facility if it is part of the facility's written SOP for handling complaints. If a facility is unable to resolve a serious complaint to the consumer's satisfaction, the consumer may file the complaint with the facility's accreditation body.

1. A serious complaint is defined as a report of a serious adverse event, which means an event that significantly compromises clinical outcomes, or one for which a facility fails to take appropriate corrective action in a timely manner.

2. Examples of serious adverse events include: poor image quality, missed cancers, the use of personnel who do not meet the applicable requirements of 21 CFR 900.12 (a), and failure to send mammography reports or lay summaries to the appropriate person(s) within 30 days.

(c) The consumer needs to be able to obtain adequate directions from the facility for filing serious complaints with the AB. The AB and/or a consumer may forward a serious complaint to VHAMO.

(10) **Repeat Analysis.** During inspections of Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), accredited hospitals may encounter the following situation regarding the mammographic repeat analysis. Under JCAHO requirements, the repeat analysis is to be performed on the basis of each individual technologist, rather than being based on the entire facility as is the present MQSA standard. FDA has determined that the JCAHO system is substantially equivalent to the MQSA standard (as long as the analysis is performed at least quarterly) and therefore meets the MQSA requirement.

## 9. ADDITIONAL MAMMOGRAPHY REVIEW (AMR)

a. **Background.** AMR was developed to assist officials in determining the appropriate response when inspections show a L1 finding for phantom image testing, interpreting physician qualifications, or an area of similar criticality. A L1 finding represents a key deviation from standards that may seriously compromise the quality of mammography services offered by the facility. **NOTE:** *It has been determined that certain L1 findings are indicators that serious quality problems may be present at the facility.*

### b. Scope

(1) This guidance provides specific criteria to assist in determining the appropriate type and scope of assessment that would be necessary, and how and by whom the action needs to be conducted. The AMR helps to determine whether the facility is in compliance and, if not, whether there is a need to notify affected patients, their physicians, or the public that the reliability, clarity, and accuracy of interpretation of mammograms has been compromised.

(2) There are two specific types of AMR identified in this policy. These are AMR conducted by the Facility (AMRF) and AMR conducted by the AB (AMRAB). Under AMRF, VA works with the facility to identify qualified interpreting physicians who would perform the AMR. **NOTE:** *The physician(s) are subject to VHA Central Office approval.* Under AMRAB, the facility's AB would be asked to conduct the AMR.

### c. Procedures

(1) If there is substantial belief that mammography quality at a facility has been compromised and may present a serious risk to human health, the facility must provide clinical images and other relevant information, as specified by VA, for review by the AB or other entity designated by VA.

(2) If VA determines that any activity related to the provision of mammography at a facility may present a serious risk to human health such that patient notification is necessary, the facility must notify patients or their designees, their physicians, or the public, of action that may be taken to minimize the effects of the risk. Such notification must occur within a timeframe and in a manner specified by VA.

**NOTE:** *Conflict of Interest. The interpreting physician(s) conducting the image review for AMRF or AMRAB should not have a relationship with the facility, nor should they conduct the review when it would otherwise be a conflict of interest for them to do so, or when they have a bias in favor of or against the facility.*

e. **Fees.** Before the facility's AB conducts AMRAB, the AB may require reimbursement of their expenses for the AMRAB. In this case, the AB needs to notify the facility accordingly,

including an estimate of the cost to conduct the AMRAB. The AB may also require payment from the facility prior to the start of the AMRAB.

f. **AMRF**

(1) **L1 Findings.** If a facility has serious L1 finding(s), but there is no other evidence of serious problems relating to the mammography program, then it may be asked to conduct AMRF. VA may suspend the certificate pending consideration of permanent mammography unit closure.

(2) **AMRAB.** If a facility has serious L1 finding(s) and there is other evidence of serious problems relating to the mammography program, then VA may require the facility to undergo AMRAB.

(3) **Follow-up Actions by VA with the Facility**

(a) If the conditions are met for an AMRF (i.e., there is no other evidence of serious problems relating to image quality), VHAMO sends a Warning Memorandum to the facility. The memorandum requires that the facility conduct an AMRF in response to the findings. The memorandum also indicates that the facility is responsible for any costs associated with the conduct of the AMR.

(b) If an AMRF is to be conducted, VHAMO monitors the progress of the review until completion. **NOTE:** *The review of images under AMRF could be on-site at the facility or by mail.*

(c) VA may suspend the certificate pending consideration of permanent mammography unit closure, or may confer with the AB as to whether the AB needs to undertake an AMRAB. VHAMO may send a Warning Memorandum to the facility that would indicate that VA had asked the facility's AB to conduct an AMRAB in response to the inspection findings.

(d) For both an AMRF and an AMRAB, the review needs to cover a sample of mammographic examinations, reports, QC and/or QA, and documentation produced using the same equipment (x-ray system and processor) that was tested and found to fail evaluation during the inspection.

1. The review needs to be retrospective and start with the last set of mammographic images produced prior to the failure and/or deficiency and proceed backward to earlier examinations.

2. The review needs to concentrate on examinations conducted as close as possible to the date and time of the inspection.

3. The review needs to encompass the appropriate number of examinations needed to effectively evaluate the impact on mammographic quality and on the mammography program.

*NOTE: The decision for the time period covered for the AMR needs to be based on public health considerations for the patients who were examined.*

(e) The AMR needs to consist of reviewing a sample of QC and/or QA documents; mammograms (or all of the mammograms, if appropriate) from the specified period, and other documentation as necessary. Depending on the results of the review, the review may be extended.

(f) The review of images and documents under an AMRAB is on-site at the facility or by mail, as determined by the facility's AB in consultation with VHAMO.

(g) If the results of the AMRF or AMRAB indicate that the quality of mammographic images, interpretations, or other documents at the facility represent a serious risk to human health, the entity performing the AMR is to notify VHAMO who in turn, notifies the AB in the case of an AMRF). If appropriate, VHAMO may ask the facility to undertake notification of patients and/or referring physicians. If the facility does not have the means to perform a patient notification (PN), VHAMO needs to initiate other actions.

(h) VHAMO coordinates implementation and monitoring of the notification process.

(i) If the results of the AMR do not indicate a serious risk to human health, the entity performing the AMR needs to notify VA (VA would notify the AB in the case of an AMRF). VA evaluates the results of the AMR and determines if additional follow-up or monitoring is necessary. VA might request the AB continue to perform close monitoring of this facility. In the case of an AMRF, VA may request the AB to perform its own AMR.

## 10. INTERVENTIONAL STEREOTACTIC BREAST PROCEDURES

a. **Purpose.** This paragraph provides direction and guidance in the performance of stereotactically guided breast interventional procedures utilizing a mammography equipment interface such as an add-on unit to the mammography machine or a dedicated prone table.

b. **Background.** ACR currently has published a standard for Stereotactically Guided Breast Interventional procedures, a Stereotactic Breast Biopsy QC Manual and has established a Stereotactic Biopsy Accreditation Program. Under current Federal law, a mammographic modality means a technology for radiography of the breast. Stereotactic interventional procedures in the breast are currently exempt from the definition of mammography and, therefore, the requirements of the final mammography regulations. However, mammography equipment is utilized to determine the proper stereotactic intervention or placement has occurred. Since mammography equipment is used in these procedures, it logically follows that the same assurances need to be provided and care taken to determine the accuracy, maintenance and functioning of this equipment.

c. **Scope**

(1) At such time that Federal law and standards are passed which cover mammographic stereotactic breast interventions, all VA facilities providing on-site stereotactic breast interventions are expected to meet those standards. During the interim period, prior to standardized Federal regulations, the following guidelines attempt to define principles of practice, which are needed to produce high-quality radiological care. **NOTE:** *These strategies need not be deemed inclusive of all proper methods of care or exclusive of other methods of care.*

(2) All VA facilities obtaining stereotactically-guided breast interventional procedures from non-VA community facilities must ensure the facility is accredited by the ARC American College of Surgeons Stereotactic Breast Biopsy Accreditation Program for that respective procedure.

d. **Equipment Specifications and Assessment Methods**

(1) Radiographic equipment that can be used for stereotactically guided percutaneous breast interventional procedures include prone stereotactic units and add-on stereotactic devices for dedicated mammographic units. The equipment needs to be calibrated by the manufacturer at the time of installation. The qualified medical physicist needs to complete verification of calibration and acceptance testing before use.

(2) At a minimum, VA facilities performing on-site stereotactic guided breast interventional procedures must have the stereotactic equipment surveyed by the medical physicist. The QC testing performed by the medical physicist and the mammography technologist needs to be substantially the same as that described the ACR Stereotactic Breast Biopsy Quality Control Manual until that document is superceded by national Federal standards and guidance. New equipment must be surveyed prior to being put into use, and existing equipment must be evaluated and calibrated at the same time the annual mammography physicist's survey is performed.

e. **Qualifications and Responsibilities of Personnel**

(1) **Interpretative Experience.** Interpretative experience in screening and diagnostic mammography is essential for those performing stereotactically-guided Fine Needle Aspiration (FNA) or Core Needle Biopsy (CNB). Prior to the stereotactic procedure, the physician needs to be able to identify the significant lesion(s) on mammography so that the correct area of the breast is localized or biopsied. This is particularly important when small field-of-view imaging equipment is employed. **NOTE:** *Technologists and physicists need specialized skills to optimize their participation in this procedure.*

(2) **Standards for Physicians, Physicists, and Radiologic Technologists.** Qualifications for physicians, physicists, and radiologic technologists need to be in compliance with the MQSA

final regulations effective April 28, 1999, the ACR Standard for the Performance of Screening Mammography, and the ACR Standard for the Performance of Diagnostic Mammography.

(3) **Specific Qualifications for Stereotactic Guided Biopsy.** In addition to the qualification requirements stated in the preceding paragraph, the following specific qualifications for personnel participating in stereotactic biopsy are recommended:

(a) Physician. Three hours of Category I CME didactic instruction in stereotactic biopsy initially. Completion of a residency program that includes instruction in stereotactic breast needle procedures is also acceptable. For maintenance of competence, there is to be documentation of the performance of an average of at least twelve stereotactic biopsies per year.

(b) Radiologic Technologist. Initially, 3 hours of ARRT Category A CEUs in stereotactic biopsy, plus documentation of five hands-on procedures under the guidance of a qualified technologist, and/or the manufacturer's application specialist. For maintenance of competence, there should be documentation of the performance of an average of at least twelve stereotactic biopsies per year.

(c) Qualified Medical Physicist. Three hours of continuing education in stereotactic biopsy unit physics, documentation of physics surveys of at least two units or hands-on training under the guidance of a qualified medical physicist, and the performance of at least one survey of a stereotactic unit each year.

**f. Guidelines for Transportation of Patients Undergoing Open Breast Biopsy After Needle Localization**

(1) The biopsy procedure needs to be performed at the same facility as the mammographic needle localization, preferably in the same building. If transportation to an adjacent building is required, it needs to be accomplished via gurney or wheelchair, preferably by way of enclosed conduits. Transport by motor vehicles is to be avoided.

(2) The biopsy procedure needs to be performed at the same facility, preferably in the same building, as the mammographic wire localization procedure. If transportation to an adjacent building is required, the patient needs to be transported via gurney or wheelchair, preferably through enclosed conduits. 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.

(3) After confirming position of the localizing needle, a protective cup-like shield needs to be carefully secured, over the protruding portion of the localizing needle, to the surrounding breast or chest wall with adhesive strips. If the exposed portion of the localizing needle is too long to permit this, it needs to be carefully bent one to two centimeters above the puncture site until the excess wire is roughly parallel to the skin. The wire then needs to be gently secured to the skin with a strip of light duty adhesive tape.

(4) After confirming the position of the localizing wire, the wire needs to be secured gently to the surrounding skin with a strip of light duty adhesive tape. Further protection against wire dislodgement may be provided by carefully securing a cup-like shield over the protruding portion of the wire.

(5) The patient needs 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.

(6) Only standard examining gowns and bed sheets are to be used for patient comfort and modesty. Blankets and outerwear must be avoided.

(7) The patient needs to avoid moving the ipsilateral arm. Examining gowns needs 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.

(8) The procedure needs 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.

**g. QC and Improvement, Safety, Infection Control, and Patient Education Concerns**

(1) **QC Program.** A documented QC Program with procedure manuals and records for stereotactically guided pre-operative localizations, FNAs, and CNBs, needs to be maintained. The quality improvement and/or QC Program needs to include regular meetings of the entire team, including the radiologist, technologist, and medical physicist. Results of stereotactically guided and other imaging-guided percutaneous breast interventional procedures need to be monitored.

(2) **Records.** Records need 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 need to be recorded.

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

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

(3) **Policies And Procedures.** Policies and procedures related to quality, patient education, infection control, and safety need to be developed and implemented in accordance with the ACR Policy on Quality Control and Improvement, Safety, Infection Control, and Patient Education Concerns.