

MAMMOGRAPHY SERVICES
QUALITY ASSURANCE:
BASELINE STANDARDS FOR
LATIN AMERICA AND THE
CARIBBEAN



Pan American
Health
Organization



World Health
Organization

REGIONAL OFFICE FOR THE

Americas

MAMMOGRAPHY SERVICES
QUALITY ASSURANCE:
BASELINE STANDARDS FOR
LATIN AMERICA AND THE
CARIBBEAN



**Pan American
Health
Organization**

Washington, D.C., 2016



**World Health
Organization**

REGIONAL OFFICE FOR THE **Americas**

Original versión in Spanish:

Garantía de calidad de los servicios de mamografía; Normas básicas para América Latina y el Caribe

ISBN: 978-92-75-31926-0

PAHO HQ Library Cataloguing-in-Publication Data

Pan American Health Organization

Mammography Services Quality Assurance: Baseline Standards for Latin America and the Caribbean.

Washington, D.C. : PAHO, 2016.

1. Mammography – standards. 2. Mammography – methods. 3. Human Resources. 4. Equipment and Supplies. 5. Health Care Quality, Access, and Evaluation. 6. Americas. I. Title.

ISBN: 978-92-75-11926-6

(NLM Classification: WP 815)

© Pan American Health Organization, 2016

All rights reserved. Publications of the Pan American Health Organization (PAHO) are available on the PAHO website (www.paho.org). Requests for permission to reproduce or translate PAHO publications should be addressed to the Publications Program through the PAHO website (www.paho.org/permissions).

Publications of the Pan American Health Organization enjoy copyright protection in accordance with the provisions of Protocol 2 of the Universal Copyright Convention. All rights are reserved.

The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of the Secretariat of the Pan American Health Organization concerning the status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by the Pan American Health Organization in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by the Pan American Health Organization to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall the Pan American Health Organization be liable for damages arising from its use.

MAMMOGRAPHY SERVICES QUALITY ASSURANCE: BASELINE STANDARDS FOR LATIN AMERICA AND THE CARIBBEAN

TABLE OF CONTENTS

I. INTRODUCTION	1
WHO guideline on mammography screening	3
Organization of health services for the provision of mammography services	3
II. MAMMOGRAPHY QUALITY ASSURANCE PROGRAM	7
Mammography service requirements	8
Mammography exam protocol	10
General information on how to perform the mammography exam	11
III. HUMAN RESOURCES FOR MAMMOGRAPHY	13
Roles & responsibilities	14
Mammography technologists	14
Radiologist/interpreting physician	16
Medical physicist	16
Radiation protection officer	17
Clinic support staff	18
Mammography program manager	18
Qualifications for mammography personnel	19
Mammography technologists	19
Interpreting physician (radiologist)	20
Medical physicist	20
IV. MAMMOGRAPHY EQUIPMENT	23
Types of mammography units	25
Numbers of mammography units needed for establishing a screening program	26
Components of the mammography equipment	26
Equipment and clinical quality control tests	28
Mammography unit and ancillary equipment quality control tests	28
Annual medical physicist's quality control tests	29
Radiologic technologist routine quality control tests	29
Clinical quality control	30
Mammography mobile units: considerations and issues	30
Used mammography equipment	31
V. COMMUNICATING RESULTS TO PATIENTS	33
Patient feedback system	35
GLOSSARY	37
REFERENCES CITED IN THE TEXT	41
RECOMMENDED READING	43



ACKNOWLEDGMENTS

This manual was produced by the Department of Noncommunicable Diseases and Mental Health and the Department of Health Systems and Services of the Pan American Health Organization/World Health Organization (PAHO/WHO), together with a group of experts from the Americas region. PAHO/WHO expresses its gratitude for the contributions of the authors (listed in alphabetical order): Helen Barr, Susana Blanco, Priscilla Butler, Maria Angela da Paz, Ileana Fleitas, Craig St George, Pablo Jiménez, Silvana Luciani, Javier Manrique, Jonathan Mazal, Kayiba Medlen, Collie Miller, Patricia Mora, Martha Moreno, Murrie Mosodeen, Gustavo Mysler, Bernardo Nuche-Berenguer, Mary Pastel, Miguel Pinochet, Gale Sisney, César Ruiz Trejo, Mona Saraiya, Esteban Solís, and Phillip Swann.

PURPOSE OF THE MANUAL AND INTENDED AUDIENCE

This manual on *Mammography Services Quality Assurance: Baseline Standards for Latin America and the Caribbean* is a guidance document for public health professionals, health authorities, and radiology personnel working in breast cancer screening programs and mammography services. It has been developed to complement the WHO Position Paper on Mammography Screening (WHO, 2014), although the information in this document is equally applicable to screening and diagnostic mammography services. The aim of this manual is to provide baseline standards on mammography quality assurance, in order to increase access to quality services, while ensuring patient and public safety. This manual includes general information on how to plan and implement a mammography quality assurance program, with specific reference to standards, indicators, human resource requirements, and equipment requirements. With the understanding that mammography services are generally part of diagnostic imaging services, this guide is intended for use in public and private health systems where mammography services are established, or are in the process of being established. This guide is not intended to be a comprehensive handbook or textbook on mammography quality control. For this purpose, a bibliography with more extensive references on mammography quality assurance is provided at the end of this manual.



I. INTRODUCTION

KEY MESSAGES

- ▶ Early detection for breast cancer, linked to appropriate and timely treatment, can significantly reduce mortality.
- ▶ Mammography is the most effective proven imaging technology for breast cancer screening, and is also used as a diagnostic tool for symptomatic patients or those with a positive screening mammogram.
- ▶ For breast cancer screening, the World Health Organization recommends organized population-based mammography screening programs for women aged 50-69 years, every 2 years. This applies to well-resourced settings and to limited resource settings, where there is a strong health system with conditions for implementing an organized screening program.
- ▶ To be effective, mammography requires a quality assurance program aimed to produce high-quality images, ensure patient safety, and provide timely treatment. This involves having qualified and trained human resources with opportunities for continuing education.

Breast cancer is the most common cancer in women and the second leading cause of cancer deaths in the world. While the direct causative agents of breast cancer remain largely unknown, awareness, early detection, accurate diagnosis, timely treatment and palliative care are the strategies to reduce the breast cancer burden. Screening and early diagnosis, coupled with advances in treatment, have led to better outcomes and longer survival for women with breast cancer.

Nonetheless, each year approximately 152,000 women are diagnosed and 43,000 women die from breast cancer in Latin America and the Caribbean. Despite the fact that, in other world regions, mammography has led to earlier diagnosis and reductions in breast cancer mortality, many Latin American and Caribbean countries face challenges with sustained implementation of quality mammography services and with making these services accessible to a significant percentage of the population. Mammography is also associated with potential harms such as radiation exposure, and false positive results that may subject the patients to unnecessary additional tests.

Due to its non-invasive nature and relatively low radiation dose, mammography is utilized both as a screening tool for asymptomatic women and as a diagnostic tool for symptomatic women. However, mammography requires not only dedicated and well-maintained equipment, but also well-trained professionals able to both obtain high-quality images and provide timely and accurate diagnosis.

Regardless of whether it is being used as a screening or diagnostic tool, the quality of mammography and the skills of the human resources are a key factors in its effectiveness, efficacy, and, when certain minimal standards of quality are not fulfilled, its accuracy is dramatically reduced, increasing the harms (e.g. radiation exposure and false positive results) and reducing the benefits to both patients and health systems.

Why Mammography?

- ▶ Sufficient scientific evidence is available to support the use of mammography, for diagnostic and screening purposes, to reduce breast cancer mortality.
- ▶ Mammography is an effective tool to detect breast cancer in its earliest, most treatable stages.

WHO GUIDELINE ON MAMMOGRAPHY SCREENING

WHO recently undertook an extensive evidence review and issued a position paper on mammography. This review shows that mammography screening programs can reduce breast cancer mortality by approximately 20% [1]. But mammography screening, as with many screening tests, can lead to false positive/negative results, which have been estimated to be approximately 20% for mammography screening [1]. Mammography screening can lead to overdiagnosis as well. However, overdiagnosis estimations vary greatly (0-54%) [2] and this estimation depends on the method used (i.e. incidence-based or modeling) [3]. Therefore, at this time, there is significant uncertainty about the quantitative estimates of overdiagnosis in the different age groups. Based on the review, WHO recommends the following mammography screening guidelines [1]:

- ▶ In well-resourced settings, organized population-based mammography screening programs are recommended for women aged 50-69 years, every 2 years. In these settings, screening programs for women 40-49 years of age and 70-75 years of age are suggested only if conducted in the context of rigorous research, monitoring, and evaluation.
- ▶ In limited resource settings with relatively strong health systems, organized population-based mammography screening programs are suggested for women aged 50-69 years, every 2 years only if the conditions for implementing a screening program are met. In these settings, WHO does not recommend population-based mammography screening of asymptomatic women 40-49 years of age and 70-75 years of age.
- ▶ In limited resource settings with weak health systems, organized population-based mammography screening programs may not be cost-effective and feasible. Early diagnosis of symptomatic women with prompt diagnosis and treatment should be the priority. In these settings, clinical breast examination seems to be a promising screening approach.

ORGANIZATION OF HEALTH SERVICES FOR THE PROVISION OF MAMMOGRAPHY SERVICES

Mammography services should be integrated in well-structured health systems and services that provide follow-up care and access to treatment. There are well-established health service conditions that are needed for quality mammography services (described in the following table).

CONDITIONS FOR QUALITY MAMMOGRAPHY (WHO, 2014)

- ▶ Sufficient health system and financial resources to sustain mammography services and assure diagnosis and treatment.
- ▶ Acquisition and maintenance of mammography equipment, appropriate for the resource level, along with the necessary infrastructure, supplies, qualified health personnel (mammography technologist, medical radiologist, and medical physicist), and quality assurance program.
- ▶ A managerial/administrative structure responsible and accountable for quality assurance, and evaluation of the overall mammography services.
- ▶ Adherence to evidence-based guidelines for mammography that include standards for quality assurance.
- ▶ Validated protocols for all steps in the mammography process, including identification of the population and invitation of eligible women to attend mammography (for screening); a referral system for mammography; performing mammography and assuring its quality, including proper positioning; high-quality imaging; acceptable radiation dose; and timeliness of results.
- ▶ Communication and education of the population and providers, with culturally appropriate, balanced, and objective information about mammography benefits and harms.
- ▶ Information system to record data in the mammography process, including call and recall of participants for follow-up of abnormalities.
- ▶ Regular monitoring, evaluation, and reporting of mammography program performance and impact, using process and outcome indicators, including women's safety and satisfaction.

The objective of a mammography quality assurance program is to ensure the production of high-quality images, with the least possible amount of radiation exposure that will allow the radiologist to accurately detect breast cancer or other breast pathologies. Achieving this objective, whether it is for diagnostic or screening mammography, is fundamental to accurately detect breast cancer, identifying proper treatment and reducing breast cancer mortality. High-quality care should be ensured at every level and stage of the mammography process, from the selection of the target population to the final diagnosis. This includes the availability of mammography equipment, its correct use and maintenance, the accurate interpretation of images, and diagnosis. The provision of mammography services should be implemented strategically to meet a country's need, depending on the availability of necessary resources.

It may be useful to first introduce mammography services through small pilot programs and expand these services, as resources permit. Equity is critical, and all women should have equal access to mammography services, follow-up diagnostic imaging and pathology services as required, and equitable and affordable access to evidence-based treatment. Quality standards should be consistent across all locations of mammography services, including in public and private health services.

The provision of quality mammography services is a shared responsibility of the health, education, and other relevant government sectors. Their coordination and communication are key to successfully establishing and implementing basic quality standards for mammography services.



II. MAMMOGRAPHY QUALITY ASSURANCE PROGRAM

KEY MESSAGES

- ▶ A mammography quality assurance program is an organized effort to ensure the production of high-quality images for accurate interpretation, with the least possible radiation exposure to the patient.
- ▶ To ensure quality mammography, written procedures, protocols, and policies should be in place for the following items: facility and staff requirements, staff roles and responsibilities, patient reception, collection of patient information and maintaining patient confidentiality, image taking, image identification, image quality, quality control of equipment, maintenance of the equipment, radiation doses, record keeping, reporting and notifying of results, follow-up of results and outcome monitoring, facility assessments, and service audits.
- ▶ With a quality assurance program, mammography services will meet regulatory requirements from external bodies (e.g. national health regulatory agency)
- ▶ Quality assurance also includes good communication between patients and service providers. For example, from the moment patients walk into the mammography facility, to the moment patients receive their results, they should be treated in a professional, respectful, and sensitive manner. Patients' records should be properly labeled, stored, and privacy ensured.
- ▶ The mammography exam should strictly follow guidelines that ensure radiation safety and reliability.

A quality assurance program, with written procedures, should be established in the mammography facility prior to initiating services. The objective is to ensure the production of high-quality images for accurate interpretation, with the least possible radiation exposure to the patient. For this purpose, a well-trained team, including clinical and support staff, with well-maintained equipment, specifically designated for mammography, are essential.

MAMMOGRAPHY SERVICE REQUIREMENTS

Mammography services can be provided in fixed facilities (hospital or clinic) or in mobile mammography services (i.e. the mammography truck travels to various locations). Regardless of how the service is delivered, quality standards should be implemented to ensure patient and staff safety and adequate functioning of the equipment. Mobile mammography services, however, require special attention for quality assurance, given that transportation and inadequate installation can affect the functioning and safety of the mammography equipment. For this reason, the mobile mammography units require more frequent quality control testing.

The considerations for maintaining high-quality mammography facilities include the following:

- ▶ **Specifically designed mammography equipment:** Mammography equipment should be dedicated and exclusively used for mammography exams or procedures. Corrective and preventive maintenance procedures should be in place.
- ▶ **Temperature and humidity:** The mammography equipment must be placed in dedicated areas with stable conditions of temperature and humidity, as specified by the manufacturer's instructions. This is important because changes in these parameters can affect the equipment and result in poor image quality. For example, the room or the mobile unit that houses the mammography equipment should be air conditioned or heated to maintain air temperature for the optimal performance of the equipment. This is critical for digital mammography (DR) equipment, even when the equipment is not in use, since it is particularly sensitive to changes in temperature and humidity and electronic circuits can be damaged. It is extremely important that facilities adhere to the manufacturers' instructions.
- ▶ **Ensuring radiation protection:** Facilities should strictly follow radiation protection policies for patients, clinic staff, and the general public to ensure safety. For example, displaying warning signs of radiation, such as "X-ray in Use," and following special procedures for women who may be pregnant, including use of appropriate lap shielding, can be useful. In addition, the facility should follow diagnostic reference levels for protection of patients, based on wide scale surveys, or on published values that are appropriate for the local circumstances.¹

¹ For more information on radiation protection procedures and standards, refer to the International Basic Safety standards published by the IAEA (2014)

- ▶ **Ensuring patient privacy:** Patient privacy should be assured with secure exam rooms, available gowns, private dressing rooms, and closets to store personal belongings. Patient privacy will reduce the stress and result in better satisfaction with the service.
- ▶ **Correct identification of the patient or labeling:** Patient identification, current/updated medical history, and additional documentation should be collected. The patient medical history will provide additional details on the patients' condition whereas the personal information will allow the facility to contact the patient in case of a callback and for the delivery of the exam results. Patient records, including reports, medical history forms, and patient images/films should be properly stored and labeled. The mammography technologist should ensure that the mammography images have the patient name, date of birth, ID number, positioning views, date of the exam, and the mammography technologist's name or initials. The labels should not obscure or cover any part of the images.
- ▶ **Dedicated areas to interpret mammograms, or reading room:** An area dedicated to reading mammograms should be available, and independent of the mammography procedure room. This is to ensure the protection of staff and patients from unnecessary radiation exposure. Interpretation or reading rooms should have basic recommended viewing conditions, such as appropriate lighting and specific monitors (e.g. noise levels of image), that are conducive to reading or interpreting images.
- ▶ **Quality and storage of supplies:** All the necessary supplies to maintain an ongoing mammography service must be stored in appropriate conditions, with the correct temperature, humidity, dust control, and prevention of radiation leaks (for films or computed radiography (CR) cassette). There should be a constant management and flow of supplies to prevent interruption of the services, with a responsible person overseeing this process. In addition, expiration dates must be monitored to avoid using expired ancillaries.
- ▶ **Electric supply:** Electricity should be available with no interruptions. Power outages and fluctuations may damage the mammography equipment, affect its performance, or negatively impact the storage of data and records. It is necessary to have a back-up system to supply uninterrupted power in the event of electrical problems.
- ▶ **Waste disposal:** For environmental considerations, country regulations should be followed for the correct disposal of processor chemicals and waste from mammography services.

- ▶ **Disinfection/infection prevention and control:** Infection control procedures of the health system should be followed, including hand washing and cleaning the unit, the compression paddle and the room. Special consideration should be given to appropriate sanitizing processes after the exposure of equipment to bloody or bodily fluid, for potential contamination of the machine and to avoid the transmission of infections. Countries with no infection control guidelines can follow those issued by the WHO [4].
- ▶ **Proper storage and preservation of images or films:** In order to maintain image integrity over time, as established by national regulations, proper storage of images is required. This will enable future interpretation and comparison of images.
- ▶ **Special considerations:** In imaging patients with breast implants, referral to a facility is suggested where mammography technologists have been specifically trained and are capable of performing such procedures.

MAMMOGRAPHY EXAM PROTOCOL

Prior to the exam, the procedures should be clearly explained to the patients and any inquiries answered. Women should be given instructions not to wear deodorant or talcum powder the day of the examination, as it may interfere with the image. When the exam is performed, it is important to guarantee the privacy of patients to increase their comfort level.

Once the images are obtained, they should be correctly labeled with the patient's information. At a minimum, labeling should include the patient's first name and surname, personal or national ID number, date of birth, center at which the exam was performed, and date of the exam. There should be minimal delays from the time the mammography technologist performs the exam to when it is interpreted by the radiologist. The patient should be notified of the result as soon as possible (within a certain timeframe) and, in case of a BI-RADS® 4 or 5 [5], the diagnosis should be forwarded to the referring physician within 3 working days and to the patient within 3-5 working days. If the mammography technologist notices any suspicious abnormalities on the mammography image, the radiologist should be notified as soon as possible. These two last steps are extremely important to ensure that the patient receives prompt diagnosis and, if needed, timely treatment.

GENERAL INFORMATION ON HOW TO PERFORM THE MAMMOGRAPHY EXAM

Preparation

1. The mammography room should be clean and ready for the exam. Complete the patient's medical history form and explain the procedure to the patient.
2. Start the procedure.

Perform the exam

3. Position the patient in the mammography equipment, in accordance to imaging protocols.
4. Compress the breast until the tissue is taut (gentle tapping will not indent the skin) to ensure a good quality image.
5. Utilize proper techniques for image acquisition
6. If printing digital images, print in actual size on hard copy film. Label the image appropriately, as described in the box below.
7. File images with previous images, reports, and medical history forms in medical records, while adhering to medical archive laws and regulations, if they exist.

After performing the exam

8. Notify patient, if additional views are required.

REQUIRED IDENTIFICATION ON THE MAMMOGRAPHY IMAGE

1. Name of patient, date of birth.
2. Additional patient identifier and personal or national ID number (e.g. medical record number).
3. Date of examination.
4. Standardized view and laterality codes placed on the image in a position outside the anatomic structures and not overlapping breast tissue.
5. Facility name and location (e.g. city, state, and zip code).
6. Technologist identification.
7. Cassette/screen identification.
8. Mammography unit identification, if more than one unit in the facility.



III. HUMAN RESOURCES FOR MAMMOGRAPHY

KEY MESSAGES

- ▶ Quality mammography services are a coordinated effort that requires at a minimum a mammography technologist, a radiologist/interpreting physician, and access to a medical physicist.
- ▶ It is essential that all human resources meet the education and continuing education requirements to maintain quality standards.
- ▶ Each person involved in the mammography service has well-defined roles and responsibilities to ensure high-quality mammography services.
- ▶ All personnel involved should understand risk management and are required to perform their responsibilities in a manner that is safe to the patient, the general public, and themselves.
- ▶ Good communication and the inter-dependency among all health providers are important considerations that affect the quality of the mammography service.

ROLES & RESPONSIBILITIES

A quality mammography service is a coordinated effort that requires the participation of the main professionals: mammography technologist, radiologist/interpreting physician and medical physicist, as well as maintenance personnel. For radiation safety, while a national regulatory authority commonly regulates this, the facility manager is responsible to ensure that the appropriate licenses are obtained and standards are met. While the licensee is legally responsible for all aspects of the mammography facility, the radiologist/interpreting physician is responsible for the overall clinical aspects of the services provided. In addition, the medical physicist is responsible for the technical aspects of the mammography equipment. Duties and responsibilities should be well defined and communicated. There should also be regular communication between health professionals, other providers, and patients. The facility manager should assign the roles and specific responsibilities of the staff for quality assurance.

Mammography technologists

Mammography technologists are radiographers that take mammography images through proper positioning and the use of X-rays to assist in the diagnosis and treatment of breast disease. Their ultimate objective is to provide the radiologist with high-quality images suitable for interpretation, while ensuring the patient's safety and comfort.

The mammography technologist should be trained to perform the following tasks: optimal patient positioning, image acquisition, image processing, adherence to infection control guidelines, and ensure that all assigned quality control and quality assurance tasks are performed in a professional and verifiable manner. The technologist is required to advise the lead mammography technologist or chief radiologist of any problems and concerns affecting the quality and/or safety of the mammography services.

The main responsibilities of the **mammography technologist** should include the following:

1. **Patient care:** Completing and signing the patient medical history form and reviewing/explaining the procedure to patients. Maintaining patient comfort and safety during the exam and maintain patient confidentiality.
2. **Patient positioning/performing the exam:** Performing ordered examinations in accordance with established standards of practice and protocols and adhering to quality assurance guidelines [6, 7].
3. **Ensuring safety:** Complying with all safety policies, including infection control regulations and optimizing radiation dose.
4. **Maintaining qualifications and technical competency:** Hold a degree in radiologic technology or have adequate experience in practicing mammography. Participating in continued education and in training programs required by country/state regulations.
5. **Communicating with other professionals:** Cooperating with other healthcare professionals and complying with facility policies/procedures.
6. **Quality control and assurance, and maintaining the equipment:** Performing assigned equipment quality checks and troubleshoot problems. Notifying all pertinent team members of any issues/problems with the equipment. Maintaining a clean environment in the mammography facility including the darkroom and interpretation rooms, when applicable.

7. **Participate in clinical audits** of interpreting physicians to monitor cancer detection rates, call-back rates, and other indicators.

In addition to the mammography technologist, a facility may also consider designating a lead mammography technologist and a mammography quality control technologist.

Mammography quality control technologist:

A mammography technologist is the person dedicated to quality control (QC) testing. For facilities with one mammography technologist, that person will be the QC technologist. Normally, they are expected to perform the quality control duties, but other qualified personnel may be assigned or trained to do some or all of the quality control tests. When these duties are assigned to others, the lead technologist retains the responsibility to ensure they are performed in accordance with the existing national regulations (if any), or in accordance with international recommendations.

Lead mammography technologist:

A lead mammography technologist is the person who oversees the work of all technologists in the facility. For facilities with one technologist, that person will be the lead technologist. Normally, but not necessarily, the lead mammography technologist is expected to perform quality control duties/tests, but other qualified mammography technologists may be assigned or trained to perform some or all of the tests. When these duties are assigned to others, the lead mammography technologist retains the responsibility to ensure the tests are performed in accordance with the existing national regulations (if any) or according to international recommendations.

The main responsibilities of the **lead mammography technologist** should include the following:

1. **Apprising program staff** and acting as a resource for new mammography standards and modifications to existing mammography standards and guidances.
2. **Ensuring that each technologist** has current copies of pertinent handbooks, standard operating procedures, and guidance documents dealing with mammography to include inspection, regulations, equipment quality control, and the training programs.
3. **Being the contact point** for the mammography standards inspections, in the absence of, or as a designee of, the chief radiologist or lead interpreting physician.
4. **Analyzing reports** of the QA program to identify problems and trends, and report this information to the appropriate facility management and the chief radiologist.
5. **Providing input**, if applicable, to correct deficiencies noted in QA reports and according to his/her competencies ensure that the noted deficiencies are addressed appropriately for correction and compliance.
6. **Advising the chief radiologist and lead interpreting physician** of problems and concerns affecting the quality of the images and of the work flow.
7. **Working with the medical physicist to periodically report/verify** that the program is in compliance with the inspection and regulation requirements.

8. **Reviewing required records** such as patient records, QC reports, service records, and human resources qualifications.
9. **Ensuring quality control and assurance and maintenance of the equipment is performed.**

Radiologist/interpreting physician

In the context of mammography, a radiologist who specializes in breast imaging or a general radiologist with training in mammography are the recommended interpreting physicians. The interpreting physician should be able to detect pathologies or abnormalities by interpreting/reading the mammography images and provide an accurate diagnosis. The radiologist is the overall responsible for clinical aspects of mammography quality.

The main responsibilities of the **radiologist/interpreting physician** should include the following:

1. **Reviewing and interpreting the images:** From the images obtained by the mammography technologist, the radiologist should be able to identify and interpret breast pathologies or malignancies and act as an expert imaging consultant to the referring physician.
2. **Being able to instruct the mammography technologist** to follow-up should additional imaging be needed to aid diagnosis (e.g. spot magnification views).
3. **Instructing the mammography technologists to ensure quality exams:** Assures the compliance of mammography staff in order to achieve quality standards.
4. **Collaborating with the medical physicist on image quality.**
5. **Selecting personnel** and defining and supervising their roles and responsibilities, including QA responsibilities, in writing.
6. **Ensuring the quality of mammography** images they interpret and the content of the reports. Provide frequent and consistent feedback based on the facility policies and procedures. Conducting clinical audits to include cancer detection rate, call-back rate, etc.
7. **Advise on the purchase** and location of mammography equipment and materials.
8. **Maintain qualifications and technical competency:** Hold a degree in radiology or have adequate experience in mammography practice. Participate in continuing education and training programs required by country/state regulations.

Medical physicist

The medical physicist plays a significant role in establishing and maintaining good standards of practice for mammography facilities. A qualified medical physicist on mammography service is required to survey mammography equipment and oversee the equipment-related QA practices. A medical physicist is not necessarily based in each mammography facility, but can provide assistance to more than one mammography facility [8, 9]. The physicist works with other personnel and is consulted on various aspects, such as equipment purchase, installation, performance, imaging protocols, and radiation dose/risk assessments for staff and patients.

The main responsibilities of the **medical physicist** should include the following:

1. **Performing the service's annual survey:** This includes all the annual quality control tests, such as the phantom image quality test, the other (new) mammographic modality tests, as well as an evaluation of the quality control tests performed by the technologist in order to identify problems and adverse trends and propose corrective actions.
2. **Providing the program with a report of the annual survey.**
3. **Ensuring mammography equipment evaluations** (when applicable), e.g. after equipment relocation, major equipment repairs, and acquisition of new equipment placed into service.
4. **Optimizing radiation protection and safety** including the calibration, image quality, and patient dose assessment.
5. **Providing training and oversight on quality control tests** to the mammography technologists for radiation protection and safety. May also perform the role of radiation protection officer.
6. **Maintain qualifications and technical competency:** Hold a degree in medical physics or have adequate experience in quality control tests in mammography practice. Participate in continuing education and training programs required by country/state regulations.

Radiation protection officer

The radiation protection officer is responsible primarily for occupational and public radiation protection. The role of the radiation protection officer is to reduce these risks as much as possible by monitoring and optimizing the radiation exposure, and ensuring that the legal radiation dose limits for workers and the public are met. The national regulatory body establishes the requirements for the radiation protection officer. In large medical facilities, the radiation protection officer is usually a full-time employee or staff. In small facilities, this role is often assumed by the radiologist or by the medical physicist.

The main responsibilities of the **radiation protection officer** should include the following:

1. **Providing support and advice** to staff about ionizing radiation.
2. **Making sure staff is provided with information, instruction, and training** on safe use of equipment capable of emitting ionizing radiation.
3. **Assisting in carrying out risk assessments** on ionizing radiation sources and assisting in writing security rules.
4. **Setting up a regular system** for monitoring and recording occupational radiation doses.
5. **Preparing reports and informing** the medical physicist about any radiation incident. They should also ensure that the permissions for using ionizing radiation are valid.
6. **Adhering to the rules and regulations** for using ionizing radiation.

Clinic support staff

Receptionists and clerks are very important to ensure the quality of the mammography services. Very often they are the first point of contact with the patient; therefore, their communication and interaction with the patient is important.

The main responsibilities of the ***clinic support staff*** should include the following:

- 7. Completing necessary administrative tasks:*** these include timely transcription of reports, patient appointments, billing, etc.
- 8. Communicating to the patient in a clear, respectful, and sensitive manner:*** contribute to the patient's comfort by providing accurate information regarding their appointments, billings, etc., while doing so in a sensitive manner, considering that patients are already under stress.

Mammography program manager

The program manager is in a managerial/administrative position to organize all aspects of care.

The main responsibilities of the ***mammography program managers*** should include the following:

- 1. Preparing reports and analysis:*** managers apprise the progress, adverse trends, and appropriate recommendations; maintain accurate records reflecting program activities; and work in collaboration with the administration to develop and maintain budgets and expenditures.
- 2. Supervising, evaluating, and assigning work to the support personnel:*** develop, manage, and evaluate employees, including identifying the strengths and weaknesses of the services, to optimize the program according to the existing resources.
- 3. Supporting the strategic initiatives for women's health in the area of breast imaging:*** implement the national or regional initiatives on breast imaging in their respective facilities, while communicating the initiatives to the staff. Manage financial resources and seek opportunities for revenue enhancement.
- 4. Developing, implementing, and maintaining quality assurance program for services:*** Oversee scheduling for diagnostic services for mammography. Maintain and develop procedures related to services.
- 5. Oversees storage, maintenance, and retrieval of images.***

QUALIFICATIONS FOR MAMMOGRAPHY PERSONNEL

Baseline standards for the qualification of the mammography personnel should be established and applied consistently. All mammography personnel should be qualified to perform their duties in the most effective manner.

The competence in mammography should include aspects such as breast anatomy and physiology, positioning and quality assurance/control techniques. Facilities should hire staff meeting the minimum qualifications.

Mammography technologists

Initial Requirements

The mammography technologist should have formal training in radiologic technology from a recognized institution (e.g. University or professional association, if exists) with formal exam/assessment of individual's knowledge of theory and performance of hands-on training. The dedicated quality control mammography technologist would need additional training in quality control procedures. The following aspects are recommended:

- a) Possess a degree in imaging from a recognized institution required by the respective country/state regulations.
- b) At least 40 hours of training in mammography from a recognized institution and at least 20 supervised and correct exams are required. This test supervision could be done by a supervisor technologist or by another professional with enough competence.

Continuing Experience and Education Requirements

For maintaining the certification (after the initial accreditation), each mammography technologist should do the following:

- a) Perform at least 200 exams in a 24-month period (about 8/month);
- b) Receive continuing education: 8 hours in a 24-month period (can be online retraining courses);
- c) If at least 200 exams have not been performed in the last 24 months, 20 supervised exams are required for requalification;
- d) Training in new technology: 8 hours minimum is recommended when technology is changed (this can be peer-led training).

Interpreting physician (radiologist)

The competence for radiologists in mammography should include the capacity to identify high-quality mammography images and to have the ability to distinguish between cancerous lesions, benign pathologies, and other tissues or artifacts. They also should have the ability to reject and correct images with no interpretative quality. The following aspects are recommended:

Initial Requirements

- a) Possess a medical degree from a recognized institution, with postgraduate training in radiology and sufficient training in mammography.
- b) Sufficient training in mammography involves a minimum of no less than 200 hours of training, and 200 exams interpreted under supervision in a 6-month period of time maximum.

Continuing Education Requirements

For maintaining the certification (after the initial year of accreditation), each radiologist should do the following:

- a) Perform 600 exams in a 24 month period (in patient care settings, and if not feasible, including continuing education case reviews);
- b) Continuing education: 8 hours in a 24 month period (can be online retraining course);
- c) Requalifying after absence: 200 exams performed under supervision in a 6-month period of time maximum;
- d) Training in new technology: at least 8 hours minimum, when technology is changed (can be peer-led training).

Medical physicist

Medical physicists are trained in evaluating the performance of technical performance of the mammography systems (mammography equipment, CR scanners, specialized printers, X-ray views, acquiring and interpreting monitors), as well as facility quality assurance programs and facility quality assurance programs. They should meet the qualifications for a medical physicist set forth in each country. The competence of the medical physicist should include good knowledge of the equipment present in the facility, as well as knowledge of good standards of practice equipment performance, imaging protocols, and radiation dose/risk assessments for staff and patients.

Initial Requirements

- a) Possess qualifications such as a formal training in medical physics and diagnostic imaging as required by country/state regulations (if they exist);
- b) Formal training in medical physics involves a postgraduate degree in medical physics as a minimum, or certification/recognition as a medical physicist by a recognized institution;

- c) Possess an equivalent of 30 hours of mammography training and perform 10 full mammography surveys under the supervision of a qualified medical physicist.

Continuing experience and Education Requirements

For maintaining the certification (after the initial accreditation), each medical physicist should do the following:

- a) Receive 8 hours of continuing education (can be online retraining course) and 10 full mammography surveys, in 24 months;
- b) Receive training in new technology: 8 hours minimum when technology is changed (can be peer-led training).



IV. MAMMOGRAPHY EQUIPMENT

KEY MESSAGES

- ▶ Decisions regarding the number and type (digital vs. analogue) of mammography units required should be based on a health technology assessment to determine what is appropriate for the given health system, epidemiology, and country/local context.
- ▶ The routine quality control tests and availability of well-maintained mammography equipment and all its ancillary components is necessary for ensuring high-quality mammography services.
- ▶ All components of the equipment have a defined function and should be used in an efficient manner, ensuring accuracy in the results and the safety of patients and staff.
- ▶ The incorrect use, or lack of preventive and corrective maintenance of any component of the equipment, could result in poor mammography image quality, and as a consequence could lead to a missed cancer diagnosis or excessive radiation exposure for the patients.

The mammography equipment is the core of the services. Diagnostic mammography services are generally part of a larger radiology service in an imaging facility or a hospital, while screening mammography services could be an independent infrastructure (e.g. mobile units).

Provision of quality mammography services does not only rely on the initial investments in purchasing the equipment, but also in its ongoing operation and maintenance.

It is important that the equipment goes through strict quality control tests, guaranteeing that it will provide high-quality mammography service. These quality control procedures should be applied from the initial setting up of the equipment, and continue regularly over the duration of its service life.

The trend is to substitute mammography analogue equipment with digital technology, due to product availability and technological advances. The advantages of digital technology include the immediate availability of images, potential use in tele-radiology, and possibility to share images and knowledge more widely with other health professionals. However, the decision to implement film-based or digital mammography should be taken only after a comprehensive health technology assessment.

The acquisition of mammography equipment is an important step in the establishment of the services, but the cost of maintenance should be incorporated in the initial budget in order to make it cost-effective. Other ongoing costs to consider for sustainability are staff salaries, physical infrastructure, quality control equipment, and supplies of all the products needed to perform the mammography, including films, processor chemicals, electric supply, ventilation, software, licenses, etc.

Maintenance and quality assurance affect the quality of the images, patient safety and the durability of the equipment, while protecting the investment and optimizing resources. The equipment and its ancillary components (processors, view boxes, monitors, laser printers, etc.) should be correctly utilized, maintained, and dedicated to mammography use only.

Standards for the mammography equipment and maintenance are essential, since the malfunction of any component may result in poor image quality and/or unnecessary radiation doses to the patients. There is a need to establish standards of quality and maintenance for donated/second-hand equipment. New technologies should be incorporated gradually and only when there are sufficient resources available for sustainability.



TYPES OF MAMMOGRAPHY UNITS

Mammography units are used exclusively for X-ray exams of the breast, with special accessories that allow only the breast to be exposed to the X-rays. There are two types of units: digital and analogue mammography. The patient examination is the same with both types, but the processing and management of images differ. When transitioning from analogue to digital equipment, proper training of staff should be provided (as noted in **section III**) and correct calibration should be ensured.

- ▶ **Film-based or analogue mammography units:** The screen-film image receptor uses film that should be developed in a film processor often located in a dark room. The film is then visualized on a dedicated mammography view box. These units require consumable supplies such as films, chemicals, waste disposal arrangements, etc.
- ▶ **Digital mammography units:** The screen-film and the film processor are either replaced by a phosphor-based plate and a plate reader or by a detector and an electronic system, generating a digital image that is sent to a workstation; therefore, the film processor and dark room are no longer needed. The image is displayed on a dedicated mammography monitor with appropriate spatial resolution and software to properly visualize it. There are also options for printing, archiving, or transmitting the image.

According to the image receptor, digital mammography is subdivided into CR technology and DR technology:

- ▶ **CR technology (Computed Radiography):** uses cassette with a phosphor-based plate in which is “read” by a special CR reader and visualized into an acquiring computer/monitor. Any existing analogue unit can be converted to CR.
- ▶ **DR technology (Digital Radiography):** the unit has a detector that directly generates the X-ray image and displays it on to the computer/monitor (cassette-less). This kind of technology is under continuous technological advancement, such as breast tomosynthesis. The advantages include the increased acquisition speed, allowing more exams as well as enhanced image quality for some clinical situations. Additionally, digital systems can usually be upgraded to incorporate new technologies. However, the initial capital cost is higher.

When using digital equipment, special care should be taken with the printing and archiving as it can compromise the diagnostic quality of the images. Therefore, keeping image resolution during archiving and printing is required. As a result, for the printing of clinical images, dedicated printers and image carriers designed for mammography are required. Although digital and analogue equipment have some common quality control requisites, there are also specific requirements for each of these technologies.

NUMBERS OF MAMMOGRAPHY UNITS NEEDED FOR ESTABLISHING A SCREENING PROGRAM

For a mammography screening program, the suggested number of units required per population, considering one mammography every 2 years for patients between 50-69 years old, is approximately 1 mammography unit for 100,000 population, or roughly 1 mammography unit for 5,000 screening exams per year. This is a general estimation, and a specific calculation for the country/region should be made based on the health system structure, human resource availability, type of technology available, and epidemiology of breast cancer.

In addition to the mammography unit, there are several components of the mammography equipment to be considered. A summary of mammography unit specifications and other equipment features are summarized in the table below.

COMPONENTS OF THE MAMMOGRAPHY EQUIPMENT

FEATURE	EQUIPMENT REQUIREMENT	APPLIES TO
Motion of tube-image receptor assembly	The mammography unit should be mechanically stable. The assembly should be capable of being fixed in any position where it is designed to operate. Once fixed in any such position, it should not undergo unintended motion. This mechanism should not fail in the event of power interruption.	Analogue and digital units
Image receptor sizes	Systems using screen-film image receptors should provide, at a minimum, for operation with image receptors of 18 × 24 cm and 24 × 30 cm. Systems using screen-film image receptors should be equipped with moving grids matched to all image receptor sizes provided.	Analogue units
	Systems used for magnification procedures should be capable of operation, with the grid removed from between the source and image receptor.	Digital units
Collimation or limitation of the beam limitation and light fields	All systems should have beam-limiting devices (collimators) that allow the useful beam to extend to or beyond the chest wall edge of the image receptor. For any mammography system with a light beam that passes through the X-ray beam-limiting device, the light should provide an average illumination of not less than 160 lux (15 ft-candles) at 100 cm or the maximum source-image receptor distance (SID), whichever is less.	Analogue and digital units
Magnification	Systems used to perform non-interventional problem-solving procedures should have radiographic magnification capability available for use by the operator. Systems used for magnification procedures should provide, at a minimum, at least one magnification value within the range of 1.4 to 2.0.	Analogue and digital units

Focal spot selection	<p>When more than one focal spot is provided, the system should indicate, prior to exposure, which focal spot is selected.</p> <p>When more than one target material is provided, the system should indicate, prior to exposure, the preselected target material.</p> <p>When the target material and/or focal spot is selected by a system algorithm that is based on the exposure or on a test exposure, the system should display, after the exposure, the target material and/or focal spot actually used during the exposure.</p>	Analogue and digital units
Application of compression	<p>Each system should provide an initial power-driven compression activated by hands-free controls operable from both sides of the patient.</p> <p>Each system should provide fine adjustment compression controls operable from both sides of the patient, and should have a manual emergency compression release.</p>	Analogue and digital units
Compression paddle	<p>Systems should be equipped with different-sized compression paddles that match the sizes of all full-field image receptors provided for the system.</p> <p>The compression paddle should be flat and parallel to the breast support table and should not deflect from parallel by more than 1.0 cm at any point on the surface of the compression paddle when compression is applied. Units intended by the manufacturer's design to not be flat and parallel to the breast support table during compression should meet the manufacturer's design specifications and maintenance requirements.</p> <p>The chest wall edge of the compression paddle should be straight and parallel to the edge of the image receptor.</p> <p>The chest wall edge may be bent upward to allow for patient comfort but should not appear on the image.</p>	Analogue and digital units
Technique factor selection and display	<p>Manual selection of milliampere-second (mAs) or at least one of its component parts (mA and/or time) should be available.</p> <p>The technique factors (kVp and either mA and seconds or mAs) to be used during an exposure should be indicated before the exposure begins, except when automatic exposure control (AEC) is used, in which case the technique factors that are set prior to the exposure should be indicated.</p> <p>Following AEC mode use, the system should indicate the actual kVp and mAs (or mA and time) used during the exposure</p>	Analogue and digital units
Automatic exposure control	<p>Each screen-film system should provide an AEC mode that is operable in all combinations of equipment configuration provided (e.g. grid, non-grid, magnification, non-magnification, and various target-filter combinations).</p> <p>The positioning or selection of the detector should permit flexibility in the placement of the detector under the target tissue. The size and the available positions of the detector should be clearly indicated at the X-ray input surface of the breast compression paddle. The selected position of the detector should be clearly indicated.</p> <p>The system should provide means for the operator to vary the selected optical density from the prefixed setting.</p>	Analogue units

X-ray film	The facility should use X-ray film for mammography that has been designated by the film manufacturer as appropriate for mammography and compatible with the cassette, the intensifying screen, and the developing system.	Analogue units
Intensifying screens	The facility should use intensifying screens for mammography that have been designated by the screen manufacturer as appropriate for mammography and should use film that is matched to the screen's spectral output as specified by the manufacturer.	Analogue units
Film processing in the dark room	For processing mammography films, the facility should use chemical solutions that are capable of developing the films used by the facility in a manner equivalent to the minimum requirements specified by the film manufacturer. There should not be any penetration of light in the dark room, protecting any possible entrance. The safety lamp should not overpass the maximal power indicated by the manufacturer of the security filter of the films that are being used.	Analogue units
Viewing	The reading room should be a closed area with no windows. There should not be any light source close to the visualization devices and all the lights should be indirect and with a control that allow to adjust the intensity. Viewing devices should provide enough luminance for the purpose of mammography.	Analogue and Digital units
Film masking devices	Facilities should ensure that film-masking devices, which can limit the illuminated area to a region equal to or smaller than the exposed portion of the film, are available to all interpreting physicians for the facility.	Analogue units

For more information on equipment requirements, please refer to the IAEA manuals for screen film-based and digital mammography [10, 11].

EQUIPMENT AND CLINICAL QUALITY CONTROL TESTS

Routine quality control tests are required for mammography quality assurance. They include the quality control tests of the mammography equipment, performed by the qualified medical physicist, and the maintenance of the clinical quality, which is performed by the lead mammography technologist and radiologist. Problems detected during any quality control test should be followed by corrective actions.

Mammography unit and ancillary equipment quality control tests

Annual equipment quality control tests are required for image quality, estimation of patient radiation dose, and viewing conditions. To measure some of these parameters, specialized quality control equipment is required. The medical physicist could use a set of quality control testing equipment for multiple mammography facilities. The quality control testing equipment should be considered during the purchase process for mammography equipment.

The following table provides a list of aspects for the annual medical physicist control tests for mammography services. The specific tests to be performed should be based on national protocols or internationally recognized protocols, such as those described in the Protocol for Mammography Quality Control from the IAEA [12].

ANNUAL MEDICAL PHYSICIST'S QUALITY CONTROL TESTS
Mammographic unit assembly evaluation
Collimation assessment
Evaluation of system resolution
Automatic exposure control system performance
Artifact evaluation
Image quality evaluation
Kilovoltage accuracy and reproducibility
Beam quality (half value layer) assessment
Breast exposure and AEC reproducibility
Average glandular dose
Radiation output rate
Screen-film tests
Uniformity of screen speed
Measurement of viewbox luminance and room luminance
Tests for digital (detector calibration)
Monitor and printer tests
Radiation protection surveys

Radiologic technologist routine quality control tests

The following is a list of quality control tests for film-based mammography. For digital mammography equipment, the quality control tests are specific to the equipment and described in the manufacturers' guidelines.

RADIOLOGIC TECHNOLOGIST SCREEN-FILM QUALITY CONTROL TEST	MINIMUM FREQUENCY
Darkroom cleanliness	Daily
Film processor quality control (densitometry, sensitometry, pH testing, and temperature)	Daily
Screen enhancer cleanliness	Weekly
Viewboxes (cleaning, light intensity, and homogeneity)	Weekly
Quality of phantom images	Weekly
Visual checklist of equipment and facilities	Monthly
Repeat analysis*	Quarterly
Analysis of fixer retention in film	Quarterly
Darkroom fog	Semi-annually
Screen-film contact	Semi-annually
Strength evaluation of the manual and automatic compression	Semi-annually

* Performed together with the radiologist.

CLINICAL QUALITY CONTROL

Clinical image evaluation process assessment categories include positioning adequacy, compression, exposure parameters (brightness vs. darkness), contrast, sharpness, noise, artifacts, and correct labeling. Radiologists should evaluate these parameters on every image submitted for his/her interpretation. Phantom images could also be used as an objective measure.

Repeats and recall/callback rates should be recorded and analyzed periodically, and at least every 3 months by the lead mammography QC technologist and the interpreting physician. The rates should not exceed 5%. This is an overall assessment of the exam and could be due to patient's positioning, processing, artifacts, superimposition (for the analog units), equipment issues, etc. [7, 10-14].

MAMMOGRAPHY MOBILE UNITS: CONSIDERATIONS AND ISSUES

Mobile units need to comply with all the same quality assurance standards of a static mammography service, and be used in collaboration with fixed mammography facilities. The mobile services should include communicating results in a timely manner to patients particularly for those with abnormal test results. The principal difference is that a mobile unit requires more frequent quality control checks due to the wear and tear from transportation/travel.

Quality control check considerations for mobile units include good functioning, generators, and conducting of quality controls tests upon arrival to a new location before initiating patient exams. Also, the mobile unit's mechanical capability/stability as well as environmental and equipment requirements should be considered [15].

Using mobile units has advantages and disadvantages that need to be considered carefully. For example, mobile units may be useful when the targeted populations are located in remote locations or dispersed or when the health care system is unable to sustain a fixed unit in that geographical area. A specialized truck is required to hold a mammography unit with adequate space to allow for the mechanical movements of the unit, as well as to accommodate and position the patients and ensure safety. Also, special precautions for processing chemicals properly need to be considered for analogue systems. The truck should have a good suspension system to minimize vibration/sudden movements. Temperature and ventilation should also be considered. Liquid/chemical waste should be returned to a fixed facility and properly disposed of (e.g. not discarded in the rural area).

In a mobile mammography service, concrete arrangements should be planned beforehand to ensure that results are effectively communicated to women, especially for women with BI-RADS® 4-5 [5], considering that mobile units typically serve remote/dispersed populations. Doing so will assure that these women are provided with the necessary diagnosis and treatment services.

USED MAMMOGRAPHY EQUIPMENT

When considering donations or purchasing of used mammography equipment, compliance with the country regulations on this matter should be taken into account. Consideration also should be taken for allocating adequate and appropriate financial and human resources to ensure continuity with the operation of the equipment, including preventive and corrective equipment maintenance.

Acquisition of mammography equipment through donations or used equipment can be a viable way to acquire initial mammography technology, while reducing up-front capital costs. A medical physicist should survey donated or used equipment to ensure that the equipment meets the quality control standards, and to guarantee that its use will result in a high-quality service.

The same quality assurance program and standards should apply to donated or used equipment as new equipment. Despite reduction in the initial investment, additional resources should be allocated for human resources salaries/employment, training, maintenance, and other consumables. Preventive and corrective service maintenance agreements should be a condition of accepting donations, and should be available for used/refurbished equipment.

A country should adhere to recommendations or norms on used mammography equipment if available or implemented. If the country has no regulations in this matter, the following are recommendations to ensure the quality of donated or second-hand equipment:

- ▶ **Communication with the seller/donor:** The responsible party should advise or communicate with the medical device regulator in the country (if it exists) and/or the Ministry of Health.
- ▶ **Refurbishing of the used equipment:** Used equipment should be factory refurbished and meet USA standards (for equipment donations from USA) or local regulations.
- ▶ **Involvement of the donor/seller in the qualification for use of the equipment:** the donor should do the initial quality control test, as well as train the staff and validate the quality control performance of the equipment (proof of maintenance of equipment).
- ▶ **Manuals and documentation related to the equipment:** All documentation (manuals) should be available, in a language acceptable to the user.
- ▶ **Conditions for acceptance of donated mammography equipment:** Do not accept or purchase mammography equipment unless the sustainability of the service is assured.
- ▶ **Consider the useful life for the equipment** recommended by the manufacturer and by the experts of the medical team of the receptor institution.



V. COMMUNICATING RESULTS TO PATIENTS

KEY MESSAGES

- ▶ The reporting/interpretation of mammograms by the interpreting physician should be standardized and clear to the referring physician.
- ▶ The latest BI-RADS® terminology is designed to standardize reporting, and is used by medical professionals to communicate the results of the mammography exam.
- ▶ The results of a mammography exam should be communicated in a timely manner to both referring physician and patients, especially when abnormal results are found.

Mammography results should be reported in writing and provided by the radiologist (interpreting physician) to the referring physician with a summary in lay terms provided to the patient. The report should be issued in a minimal time to reduce stress and to ensure rapid referral to diagnostic or treatment if needed. For ensuring standardized communication, the Breast Imaging-Reporting and Data System (BI-RADS®), developed by the American College of Radiology, is internationally accepted and widely used [5]. BI-RADS® divides the mammography results into different categories²:

BI-RADS® CATEGORY	OVERALL FINAL ASSESSMENT
0	Incomplete – need additional imaging evaluation and/or prior mammograms for comparison
1	Negative
2	Benign
3	Probably Benign
4	Suspicious
5	Highly Suggestive of Malignancy
6	Known Biopsy-Proven Malignancy

The following are important considerations following the mammography exam:

- ▶ Interpretation of the images should be completed within 2 weeks from the date of the exam.
- ▶ Each mammography exam/procedure needs a report. This written report should be signed by the radiologist or interpreting physician, and provided to the patient’s health care provider, with a summary in lay terms to be provided to the patient within 2 weeks of the interpretation.
- ▶ Deliver results as soon as possible when a BI-RADS® 4-5 is found. If the diagnosis or result of the mammogram is “suspicious” or “highly suggestive of malignancy”, reasonable attempts should be made to communicate with the health care provider (or patient) immediately not exceeding 1 week from the date of interpretation.
- ▶ Call back patients with BI-RADS® 0 (incomplete). Mammography exam for additional views should be rescheduled within 1 week from the date of interpretation. Specific slots should be accommodated for these call-backs.
- ▶ In the case of a BI-RADS® 3 result, where follow-up is advised, the date for the call-back exam should be provided to the patient as soon as possible. In the event that any changes in the breasts are noted prior to the call-back appointment, through self-exams or clinical breast exams, the patient should be advised to communicate immediately with the referring physician.



² See the ACR website [<http://www.acr.org/Quality-Safety/Resources/BIRADS>] for more information on BI-RADS®.

- ▶ In the event of an abnormal result, with BI-RADS® 4 and 5, the patient should be directly referred for diagnosis and treatment.
- ▶ If the technologist detects an abnormality, he/she should alert the radiologist as soon as possible.
- ▶ Patient records, which include reports/films, should be maintained for at least 5 years, but the duration will depend on the country guidelines.

BI-RADS® ASSESSMENT CATEGORIES³

INCOMPLETE ASSESSMENT	MANAGEMENT	LIKELIHOOD OF CANCER
Category 0: Incomplete – need additional imaging evaluation and/or prior mammograms for comparison	Recall for additional imaging and/or comparison with prior examination(s)	N/A
FINAL ASSESSMENT	MANAGEMENT	LIKELIHOOD OF CANCER
Category 1: Negative	Routine mammography screening	Essentially 0% likelihood of malignancy
Category 2: Benign	Routine mammography screening	Essentially 0% likelihood of malignancy
Category 3: Probably Benign	Short-interval (6-month) follow-up or continued surveillance mammography	>0% but ≤2% likelihood of malignancy
Category 4: Suspicious	Tissue diagnosis	>2% but <95% likelihood of malignancy
Category 5: Highly Suggestive of Malignancy	Tissue diagnosis	≥95% likelihood of malignancy
Category 6: Known Biopsy-Proven Malignancy	Surgical excision when clinically appropriate	N/A

PATIENT FEEDBACK SYSTEM

A patient feedback or consumer complaints process should be established in the mammography service, as part of the continuous quality improvement process. The system can be as simple as having a small card in the service to launch a complaint regarding the care or service provided. The feedback system could also be more sophisticated, such as having a qualitative survey for users to receive feedback on the satisfaction of care. This would serve to assure the quality of mammography, as well as respond to complaints or concerns from patients.

³ Reprinted with permission of the American College of Radiology (ACR). No other representation of this material is authorized without expressed, written permission from the ACR. Refer to the ACR website at www.acr.org/Quality-Safety/Resources/BIRADS for the most current and complete version of the BI-RADS® Atlas.



GLOSSARY

- ▶ **Diagnostic mammogram:** An X-ray of the breast to evaluate abnormalities seen or suspected, such as a lump, pain, thickening, nipple discharge, or an inexplicable change in breast size or shape; or as follow-up to a previously diagnosed breast cancer.
- ▶ **Diagnostic reference level:** A level used in medical imaging to indicate whether, in routine conditions, the dose to the patient or the amount of radio-pharmaceuticals administered in a specified radiological procedure for medical imaging is unusually high or unusually low for that procedure.
- ▶ **Health authority:** A governmental authority (at the national, regional, or local level) that is responsible for policies and interventions, including the development of standards and the provision of guidance, for maintaining or improving human health, and that has the legal power of enforcing such policies and interventions.
- ▶ **Health professional:** An individual who has been formally recognized through appropriate national procedures to practice a profession related to health.
- ▶ **Health screening program:** A program in which health tests or medical examinations are performed for the purpose of early detection of disease.
- ▶ **Lead interpreting physician:** the interpreting physician assigned the general responsibility for ensuring that a facility's quality assurance program meets all of the requirements.
- ▶ **License:** A legal document issued by the regulatory body granting authorization to perform specified activities relating to a facility or activity.
- ▶ **Mammogram:** Radiography of the breast.
- ▶ **Mammography service:** Comprises the radiology and diagnostic imaging services that are devoted to the practice of mammography. It is a combination of equipment and human resources aimed to apply low-energy X-rays to examine breasts. Regardless of whether it is screening or diagnostic mammography, a quality assurance program is required to maximize

the benefits and minimize the harms associated with this procedure.

- ▶ **Mammography technologist:** Radiology and diagnostic imaging technologist, or radiographer that performs mammography examinations.
- ▶ **Mammography unit:** An assemblage of components for the production of X-rays for use during mammography, including, at a minimum: an X-ray generator, an X-ray control, a tube housing assembly, a beam limiting device, and the supporting structures for these components.
- ▶ **Medical exposure:** Exposure to radiation or other harmful agents for the purposes of medical imaging, diagnosis, or treatment.
- ▶ **Medical physicist:** A health professional with specialist education and training in the concepts and techniques of applying physics in medicine, and competent to practice in a sub-field of medical physics.
- ▶ **Occupational exposure:** Exposure to radiation or other harmful agents workers incurred in the course of their work.
- ▶ **Patient:** An individual who is a recipient of services of health care professionals and/or their agents that are directed at **(a)** promotion of health; **(b)** prevention of illness and injury; **(c)** monitoring of health; **(d)** maintaining health; and **(e)** medical treatment of diseases, disorders, and injuries in order to achieve a cure or, failing that, optimum comfort and function. Asymptomatic individuals are included.
- ▶ **Public exposure:** Exposure incurred by members of the public due to sources in planned exposure situations, emergency exposure situations, and existing exposure situations, excluding any occupational exposure or medical exposure.
- ▶ **Quality assurance:** The function of a management system that provides confidence that a desired level of quality in mammography will be achieved.
- ▶ **Quality control:** A system for verifying and maintaining a desired level of quality in a mammography service that requires careful planning, use of proper equipment, continued testing, and corrective action.
- ▶ **Radiologist:** A physician specialized in radiology, the branch of medicine that uses ionizing and nonionizing radiation for the diagnosis and treatment of disease.
- ▶ **Radiology:** The medical specialty concerned with radiation for the diagnosis and treatment of disease, including both ionizing radiation such as X-rays and nonionizing radiation such as ultrasound.
- ▶ **Referring physician:** A health professional who, in accordance with national requirements, may refer individuals to another health professional/service, such as a radiological medical practitioner for medical exposure.
- ▶ **Regulatory body:** An authority or a system of authorities designated by the government as having legal authority for conducting the regulatory process of a service, including issuing authorizations.

- ▶ **Radiation dose:** A measure of the energy deposited by radiation in a target.
- ▶ **Screening mammogram:** An X-ray of the breast conducted in asymptomatic populations to detect early stages of breast cancer.
- ▶ **Technologist:** A health professional with special education and training in medical radiation technology, competent to perform radiological procedures, on delegation from the radiological medical practitioner, in one or more of the specialties of medical radiation technology.



REFERENCES CITED IN THE TEXT

1. WHO Position Paper on Mammography Screening, 2014: World Health Organization.
2. Puliti D, Duffy SW, Miccinesi G, de Koning H, Lynge E, Zappa M, Paci E, EUROSCREEN Working Group. Overdiagnosis in mammographic screening for breast cancer in Europe: a literature review. *J Med Screen*, 2012; **19**(1): p. 42-56.
3. Etzioni R, Gulati R, Mallinger L, Mandelblatt J. Influence of study features and methods on overdiagnosis estimates in breast and prostate cancer screening. *Ann Intern Med*, 2013. **158**(11): p. 831-838.
4. Practical Guidelines for Infection Control in Health Care Facilities, 2004: World Health Organization.
5. BI-RADS® 5th Edition (Quick Reference, free excerpts, other information), 2013: American College of Radiology.
6. Coronado Interis E, Anakwenze CP, Aung M, Jolly PE. Increasing Cervical Cancer Awareness and Screening in Jamaica: Effectiveness of a Theory-Based Educational Intervention. *Int J Environ Res Public Health*, 2015. **13**(1): p. 566-579.
7. Mammography Quality Control Manual, 1999: American College of Radiology.
8. Lynch-George G, Maharaj RG. Cervical Smears at Public Health Centres in Eastern Trinidad: Coverage and Follow-up, 2009-2010. *West Indian Med J*, 2014. **63**(6): p. 575-581.
9. Radiological Protection for Medical Exposure to Ionizing Radiation Safety Guide SAFETY STANDARDS SERIES No. RS-G-1.5, 2002: International Atomic Energy Agency.
10. Quality Assurance Programme for Screen Film Mammography. IAEA Human Health Series Publications N.2, 2009: International Atomic Energy Agency.
11. Quality Assurance Programme for Digital Mammography. IAEA Human Health Series Publications N. 17, 2011: International Atomic Energy Agency.
12. Control de Calidad en Mamografía (in Spanish). 2006: International Atomic Energy Agency (ARCA, OIEA).
13. Programa Nacional de Cáncer de Mama. Guía técnica de Procedimientos Mínimos de Control de Calidad en Mamografía Analógica (in Spanish). 2013. Ministry of Health Argentina.
14. Canadian Mammography Quality Guidelines. 2002: Ministry of Public Works and Government Services Canada.
15. Mammography Quality Standards; Final Rule, 1999: Food and Drug Administration.



RECOMMENDED READING:

- ▶ American College of Radiology (2015). Mammography Accreditation Program Requirements. **Available at:** <http://www.acraccreditation.org/~media/ACRAccreditation/Documents/Mammography/Requirements.pdf?la=en>
- ▶ American College of Radiology (2013). BI-RADS® 5th edition (Quick Reference, free excerpts, other information). **Available at:** <http://www.acr.org/Quality-Safety/Resources/BIRADS>
- ▶ American College of Radiology (1999). Mammography Quality Control Manual. **Available at:** <https://shop.acr.org/Default.aspx?TabID=55&ProductId=639>
- ▶ American College of Radiology (2014). Practice Parameter for the Performance of Screening and Diagnostic Mammography. **Available at:** http://www.acr.org/~media/ACR/Documents/PGTS/guidelines/Screening_Mammography.pdf
- ▶ American College of Radiology (2015). ACR Manual on Contrast Media Version 10.1. **Available at:** <http://www.acr.org/~media/37D84428BF1D4E1B9A3A2918DA9E27A3.pdf>
- ▶ Department of Veterans Affairs, Veterans Health Administration (2011). VHA Handbook Mammography Program Procedures and Standards. **Available at:** http://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2411
- ▶ US Food and Drug Administration (1999). Mammography Quality Standards; Final Rule. **Available at:** <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm094441.pdf>
- ▶ International Atomic Energy Agency (2009). IAEA Human Health Series Publications N. 2: Quality Assurance Programme for Screen Film Mammography. **Available at:** http://www-pub.iaea.org/MTCD/publications/PDF/Pub1381_web.pdf
- ▶ International Atomic Energy Agency (2011). IAEA Human Health Series Publications N. 17: Quality Assurance Programme for Digital Mammography. **Available at:** http://www-pub.iaea.org/MTCD/publications/PDF/Pub1482_web.pdf

- ▶ Ministry of Public Works and Government Services Canada (2002). Canadian Mammography Quality Guidelines. **Available at:** http://www.hc-sc.gc.ca/ewh-semt/alt_formats/hecs-sesc/pdf/pubs/radiation/02hecs-sesc267/02hecs267-eng.pdf
- ▶ Ministry of Health of Argentina (2013). Programa Nacional de Cáncer de Mama. Guía técnica de procedimientos mínimos de control de calidad en mamografía analógica. **Available in Spanish at:** http://www.msal.gov.ar/images/stories/bes/graficos/000000009cnt-06-guia_mamografia_final_WEB.pdf
- ▶ Ministry of Health of Argentina (2012). Programa Nacional de Cáncer de Mama. Manual operativo para el uso de mamografía en tamizaje. **Available in Spanish at:** <http://www.msal.gov.ar/images/stories/bes/graficos/0000000013cnt-10-Manual-operativo-de-uso-de-mamografia.pdf>
- ▶ International Atomic Energy Agency (ARCAL, OIEA 2006). Control de Calidad en Mamografía. **Available in Spanish at:** http://www-pub.iaea.org/MTCD/publications/PDF/te_1517s_web.pdf
- ▶ Secretariat of Health of Mexico (2002). Manual de control de calidad en mastografía en México. **Available in Spanish at:** <http://cneqsr.salud.gob.mx/contenidos/descargas/cama/manualCtrlCal.pdf>
- ▶ Secretariat of Health of Mexico. Subsecretariat of Innovation and Quality. National Center of Technologic Excellence in Health (2004). Guía tecnológica Num.11: Mastógrafo. **Available in Spanish at:** http://www.cenetec.salud.gob.mx/descargas/biomedica/guias_tecnologicas/11gt_mastografo.pdf
- ▶ Spanish Society of Diagnostic Breast Imaging (2014). Programa de garantía de calidad en mamografía. **Available in Spanish at:** http://www.sedim.org/nueva/wp-content/uploads/2014/10/Programa_Garant%C3%ADa_Calidad_SEDIM.pdf
- ▶ Spanish Society of Medical Physics-Spanish Radiation Protection Society (2011). Protocolo Español de calidad en radiodiagnóstico. Revisión 2011 (Aspectos Técnicos). **Available in Spanish at:** <http://www.latinsafe.org/espanol/wp-content/themes/latinsafe/educacion/guias-clinicas/protocolo-espanol-de-calidad-en-radiodiagnostico.pdf>
- ▶ European Commission, Food and Agriculture Organization of the United Nations, International Atomic Energy Agency, International Labour Organization, OECD Nuclear Energy Agency, Pan American Health Organization, United Nations Environment Programme, World Health Organization, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, IAEA Safety series no. gsr part 3, IAEA, Vienna (2014). **Available at:** http://www-pub.iaea.org/MTCD/publications/PDF/Pub1578_web-57265295.pdf
- ▶ World Health Organization (2004). Practical Guidelines for Infection Control in Health Care Facilities. **Available at:** http://www.wpro.who.int/publications/docs/practical_guidelines_infection_control.pdf



Pan American
Health
Organization



REGIONAL OFFICE FOR THE

World Health
Organization

Americas

