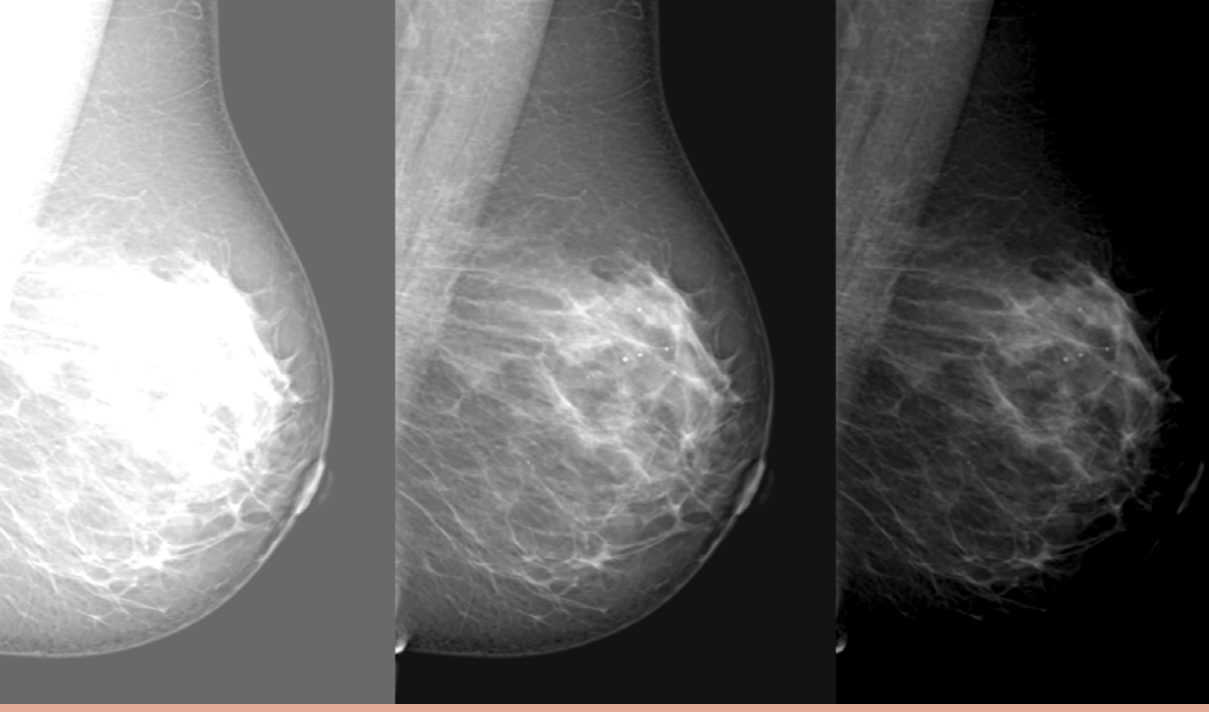

IAEA HUMAN HEALTH SERIES

No. 46

Worldwide Implementation of Digital Mammography Imaging

IAEA
International Atomic Energy Agency

IAEA HUMAN HEALTH SERIES PUBLICATIONS

The mandate of the IAEA human health programme originates from Article II of its Statute, which states that the "Agency shall seek to accelerate and enlarge the contribution of atomic energy to peace, health and prosperity throughout the world". The main objective of the human health programme is to enhance the capabilities of IAEA Member States in addressing issues related to the prevention, diagnosis and treatment of health problems through the development and application of nuclear techniques, within a framework of quality assurance.

Publications in the IAEA Human Health Series provide information in the areas of: radiation medicine, including diagnostic radiology, diagnostic and therapeutic nuclear medicine, and radiation therapy; dosimetry and medical radiation physics; and stable isotope techniques and other nuclear applications in nutrition. The publications have a broad readership and are aimed at medical practitioners, researchers and other professionals. International experts assist the IAEA Secretariat in drafting and reviewing these publications. Some of the publications in this series may also be endorsed or co-sponsored by international organizations and professional societies active in the relevant fields.

There are two categories of publications in this series:

IAEA HUMAN HEALTH SERIES

Publications in this category present analyses or provide information of an advisory nature, for example guidelines, codes and standards of practice, and quality assurance manuals. Monographs and high level educational material, such as graduate texts, are also published in this series.

IAEA HUMAN HEALTH REPORTS

Human Health Reports complement information published in the IAEA Human Health Series in areas of radiation medicine, dosimetry and medical radiation physics, and nutrition. These publications include reports of technical meetings, the results of IAEA coordinated research projects, interim reports on IAEA projects, and educational material compiled for IAEA training courses dealing with human health related subjects. In some cases, these reports may provide supporting material relating to publications issued in the IAEA Human Health Series.

All of these publications can be downloaded cost free from the IAEA web site:

http://www.iaea.org/Publications/index.html

Further information is available from:

Marketing and Sales Unit
International Atomic Energy Agency
Vienna International Centre
PO Box 100
1400 Vienna, Austria

Readers are invited to provide their impressions on these publications. Information may be provided via the IAEA web site, by mail at the address given above, or by email to:

Official.Mail@iaea.org.

WORLDWIDE IMPLEMENTATION OF DIGITAL MAMMOGRAPHY IMAGING

The following States are Members of the International Atomic Energy Agency:

AFGHANISTAN
ALBANIA
ALGERIA
ANGOLA
ANTIGUA AND BARBUDA
ARGENTINA
ARMENIA
AUSTRALIA
AUSTRIA
AZERBAIJAN
BAHAMAS
BAHRAIN
BANGLADESH
BARBADOS
BELARUS
BELGIUM
BELIZE
BENIN
BOLIVIA, PLURINATIONAL STATE OF
BOSNIA AND HERZEGOVINA
BOTSWANA
BRAZIL
BRUNEI DARUSSALAM
BULGARIA
BURKINA FASO
BURUNDI
CABO VERDE
CAMBODIA
CAMEROON
CANADA
CENTRAL AFRICAN REPUBLIC
CHAD
CHILE
CHINA
COLOMBIA
COMOROS
CONGO
COSTA RICA
CÔTE D'IVOIRE
CROATIA
CUBA
CYPRUS
CZECH REPUBLIC
DEMOCRATIC REPUBLIC OF THE CONGO
DENMARK
DJIBOUTI
DOMINICA
DOMINICAN REPUBLIC
ECUADOR
EGYPT
EL SALVADOR
ERITREA
ESTONIA
ESWATINI
ETHIOPIA
FIJI
FINLAND
FRANCE
GABON
GAMBIA
GEORGIA
GERMANY
GHANA
GREECE
GRENADA
GUATEMALA
GUYANA
HAITI
HOLY SEE
HONDURAS
HUNGARY
ICELAND
INDIA
INDONESIA
IRAN, ISLAMIC REPUBLIC OF
IRAQ
IRELAND
ISRAEL
ITALY
JAMAICA
JAPAN
JORDAN
KAZAKHSTAN
KENYA
KOREA, REPUBLIC OF
KUWAIT
KYRGYZSTAN
LAO PEOPLE'S DEMOCRATIC REPUBLIC
LATVIA
LEBANON
LESOTHO
LIBERIA
LIBYA
LIECHTENSTEIN
LITHUANIA
LUXEMBOURG
MADAGASCAR
MALAWI
MALAYSIA
MALI
MALTA
MARSHALL ISLANDS
MAURITANIA
MAURITIUS
MEXICO
MONACO
MONGOLIA
MONTENEGRO
MOROCCO
MOZAMBIQUE
MYANMAR
NAMIBIA
NEPAL
NETHERLANDS
NEW ZEALAND
NICARAGUA
NIGER
NIGERIA
NORTH MACEDONIA
NORWAY
OMAN
PAKISTAN
PALAU
PANAMA
PAPUA NEW GUINEA
PARAGUAY
PERU
PHILIPPINES
POLAND
PORTUGAL
QATAR
REPUBLIC OF MOLDOVA
ROMANIA
RUSSIAN FEDERATION
RWANDA
SAINT KITTS AND NEVIS
SAINT LUCIA
SAINT VINCENT AND THE GRENADINES
SAMOA
SAN MARINO
SAUDI ARABIA
SENEGAL
SERBIA
SEYCHELLES
SIERRA LEONE
SINGAPORE
SLOVAKIA
SLOVENIA
SOUTH AFRICA
SPAIN
SRI LANKA
SUDAN
SWEDEN
SWITZERLAND
SYRIAN ARAB REPUBLIC
TAJIKISTAN
THAILAND
TOGO
TONGA
TRINIDAD AND TOBAGO
TUNISIA
TÜRKİYE
TURKMENISTAN
UGANDA
UKRAINE
UNITED ARAB EMIRATES
UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND
UNITED REPUBLIC OF TANZANIA
UNITED STATES OF AMERICA
URUGUAY
UZBEKISTAN
VANUATU
VENEZUELA, BOLIVARIAN REPUBLIC OF
VIET NAM
YEMEN
ZAMBIA
ZIMBABWE

The Agency's Statute was approved on 23 October 1956 by the Conference on the Statute of the IAEA held at United Nations Headquarters, New York; it entered into force on 29 July 1957. The Headquarters of the Agency are situated in Vienna. Its principal objective is "to accelerate and enlarge the contribution of atomic energy to peace, health and prosperity throughout the world''.

IAEA HUMAN HEALTH SERIES No. 46

WORLDWIDE IMPLEMENTATION OF DIGITAL MAMMOGRAPHY IMAGING

INTERNATIONAL ATOMIC ENERGY AGENCY
VIENNA, 2023

COPYRIGHT NOTICE

Marketing and Sales Unit, Publishing Section
International Atomic Energy Agency
Vienna International Centre
PO Box 100
1400 Vienna, Austria
fax: +43 1 26007 22529
tel.: +43 1 2600 22417
email: sales.publications@iaea.org
www.iaea.org/publications

Printed by the IAEA in Austria
October 2023
STI/PUB/2011

IAEA Library Cataloguing in Publication Data

Names: International Atomic Energy Agency.
Title: Worldwide Implementation of Digital Mammography Imaging / International Atomic Energy Agency.
Description: Vienna : International Atomic Energy Agency, 2023. | Series: IAEA Human Health Series No. 46, ISSN 2075–3772 ; no. 46 | Includes bibliographical references.
Identifiers: IAEAL 23-01599 | ISBN 978–92–0–126723–8 (paperback : alk. paper) | ISBN 978–92–0–126823–5 (pdf) | ISBN 978–92–0–126923–2 (epub)
Subjects: Diagnostic imaging. | Diagnostic imaging — Methods. | Radiology. | Breast — Radiography. | Radiography, Medical.
Classification: UDC 615.849 | STI/PUB/2011

FOREWORD

In medical imaging, digital technologies can have many fundamental advantages over screen-film technology, such as (i) improved efficiency of the use of radiation in forming the image, which allows for dose reduction, (ii) transmission of images electronically and from archival storage in a computer system, (iii) increased robustness to exposure techniques with the disappearance of obvious under- and overexposure failures and (iv) the many image processing and other digital applications, such as artificial intelligence, that can be applied to digital images. Other practical advantages include cost reduction and replacement of chemical developers by a more environmentally friendly detector. Finally, the digital framework allows expert diagnostic judgements to be made available regardless of the distance between the imaging facility and the expert. These advantages also apply to mammography. However, in mammography, image quality is critical, and a sufficient level of quality is achieved only if system operation is optimized. A switch from screen-film to digital technology ought to be performed, therefore, only if high quality images can be guaranteed. Optimal system operation and quality control are needed at all levels including for the newest digital systems.

It has been recognized that achieving optimized imaging in mammography is a complex multifactorial process that starts with the design and implementation of a proper infrastructure and the best technology. It requires well trained staff and a rigorous quality assurance programme. While many digital imaging devices exist, there is no unique answer to the best solution in practice, given set resources. It is also recognized that there is no practical guidance on how to transition to digital technology systems. The World Health Organization (WHO) also recognized that a noteworthy number of clinical radiologists had experienced great challenges in implementing digital radiology and that radiology departments could benefit from an unbiased and independent resource to guide them in this.

In 2016, the IAEA and WHO published IAEA Human Health Series No. 28, entitled Worldwide Implementation of Digital Imaging in Radiology, a publication intended to address issues associated with the introduction of digital radiology. In response to the need to advise Member States on topics specifically related to mammography, in 2016 the Scientific Committee of the IAEA/WHO Network of Secondary Standards Dosimetry Laboratories recommended that guidance be developed for the implementation of digital mammography technologies. The present publication is a companion to Human Health Series No. 28 and provides information on the resources needed for different mammography systems.

The IAEA acknowledges the contributions of the drafting committee responsible for the development of this publication in particular, H. Bosmans (Belgium), M.E. Brandan (Mexico), R.A. Jong (Canada), M. Yaffe (Canada) and

C.H. Yeong (Malaysia). The IAEA officers responsible for this publication were H. Delis and V. Tsapaki of the Division of Human Health.

CONTENTS

1. INTRODUCTION

1.1. BACKGROUND

The incidence of breast cancer is continuing to rise, particularly in low and middle-income countries (LMICs) [1]. Mammography is widely used to facilitate the detection of breast cancer at a point earlier in its natural history than is possible by clinical examination [2]. It is also the only imaging method for the early detection of breast cancer that has been demonstrated to contribute to reduced mortality through screening [3]. Its use is increasing in LMICs as the incidence of breast cancer increases. Digital mammography systems were introduced in 2000 and offer many advantages over screen-film mammography.

1.2. OBJECTIVE

The purpose of this publication is to provide guidance on the establishment of digital mammography facilities or upgrade of existing facilities when selecting and implementing new technology for mammography imaging in different resource settings.

Guidance and recommendations provided here in relation to identified good practices represent expert opinion but are not made on the basis of a consensus of all Member States.

1.3. SCOPE

This IAEA publication is intended to assist health care policy decision makers, planners, programme administrators and professionals working in health care in establishing or upgrading capabilities for diagnostic and screening mammography. The IAEA and other organizations have published guidance around aspects related to breast cancer incidence [4], breast imaging [2], breast cancer prevention, quality assurance (QA) and quality control (QC) of screen-film [5] and digital systems [2], and QA in screening and diagnosis [6, 7]. The focus here is explicitly to inform and facilitate decisions and planning on how to select or transition mammography services to the best quality possible with available resources.

1.4. STRUCTURE

The present IAEA publication builds on existing guidance [2, 5, 8] and presents a 'road map' for how to move from any current situation to one that better addresses the needs of a community. Section 1 presents the background, objective, scope and structure of this publication. Section 2 shows a road map for a mammography facility and helps interested parties to identify the level of mammography service at which they are currently operating and the level that is feasible with upgraded services. Decision points in the road map are linked to relevant supporting information in subsequent sections and appendices. It also provides an overview of various implementation scenarios with more detailed information to facilitate making decisions. Section 3 discusses what is required to implement the different types of service, direct digital mammography (DDM), computed radiography mammography (CRM) or screen-film mammography (SFM). Aspects of equipment, infrastructure, quality needs, maintenance and staff training are included. In addition, the transition between screen-film and digital modalities is discussed in Section 4.

More detailed information is provided in the appendices as follows: Appendix I provides a review on breast cancer incidence, mortality and geographical factors as well as the principles of breast cancer screening and factors to consider before initiating a screening programme. Appendix II presents an overview of the different types of mammography technologies, including breast tomosynthesis and contrast-enhanced mammography. Appendix III reviews other breast imaging modalities such as ultrasound, magnetic resonance imaging (MRI), positron emission tomography (PET) and breast computed tomography (CT). Appendix IV reviews evaluations of physico-technical parameters that describe the performance of mammography systems and presents examples of relationships between tests and clinical performance. Appendix V reports briefly on QA and QC tests that assure the high quality performance of systems, describes metrics for digital detectors and discusses the importance of artefact evaluation as well as the use of contrast detail phantoms to evaluate system performance. Appendix VI outlines the needs for professional education and training of key personnel involved in the delivery of high quality mammography services. Finally, Appendix VII shows some examples of existing mammography evaluation programmes implemented in some countries or continents.

Ultimately, this publication potentially pertains to all people for whom the detection of breast cancer would be facilitated by mammography, but the term 'women' is used because it reflects the vast majority of the use of breast imaging.

2. A ROAD MAP FOR A MAMMOGRAPHY FACILITY

This section provides a road map to assist health care decision makers, administrators and professionals. Establishment or upgrading of a mammography service is defined by applying various scenarios before deciding further steps. The analysis includes needs for investment and maintenance, as well as the availability of infrastructure and human resources that are essential for evolution.

Figures 1–6 are decision trees for various types of medical imaging facilities, and they have been created to guide the transition from a current situation towards improved mammography services. Cross-references to the relevant section in this publication are provided to facilitate decisions.

Although there are several technical and operational advantages associated with digital systems, it is also acknowledged that there may be differences in the available economic and human resources or infrastructure (e.g. quality of electrical supply) that may impact decisions that need to be made. Several scenarios exist and are explored to depict the next steps in improvement. If there is no scenario that exactly describes a facility, the two closest scenarios can be investigated.

It is assumed as a minimum standard that, if mammography is performed, it is done using X ray equipment that is explicitly designed for the purposes of mammography in that it has the capability of producing low energy X rays (using different target/filter combinations), a small X ray focal spot, an automatic exposure control (AEC), an integrated compression device, and a mammography grid and beam collimator designed for imaging the breast. In addition, there ought to be a means available for providing the medical radiation technologist with information on the settings (kilovoltage (kV) and milliampere-seconds (mAs)) for the exposure, where the AEC system cannot be used or is uncalibrated. The system design and performance capability need to comply with the relevant current standards of the International Electrotechnical Commission (IEC) [9]. A general-purpose radiographic unit ought not to be used to carry out mammography.

2.1. IMPLEMENTATION SCENARIOS

Digital mammography plays a vital role in the diagnosis and management of breast diseases; however, its implementation needs to be carefully evaluated and justified according to the local scenario. This section discusses the practical implementation of digital mammography in multiple scenarios, such as (a) a facility that has limited resources and does not have any medical

imaging equipment; (b) a facility that has limited resources and does not have a mammography system; (c) a hospital with an SFM facility; (d) a hospital with a CRM facility; and (e) a tertiary care hospital with breast imaging.

2.1.1. No medical imaging facility

This scenario is applied to a facility (e.g. a general clinic) that has limited resources (in terms of financial, human or infrastructure constraints) and does not have any medical imaging equipment yet. In this scenario, implementing other imaging capabilities such as general radiography or CT may be a higher priority than mammography. A radiologist, medical radiation technologist and a clinically qualified medical physicist (CQMP) specifically trained in breast imaging are essential for introducing breast imaging. A facility lacking these professionals, even with general training, would have great difficulty establishing high quality mammography.

2.1.2. Limited resources — no mammography

This scenario refers to a setting where there is some general radiological imaging, but no mammography system. The term 'limited resources' may refer to financial constraints, but in some cases, it denotes a lack of human resources

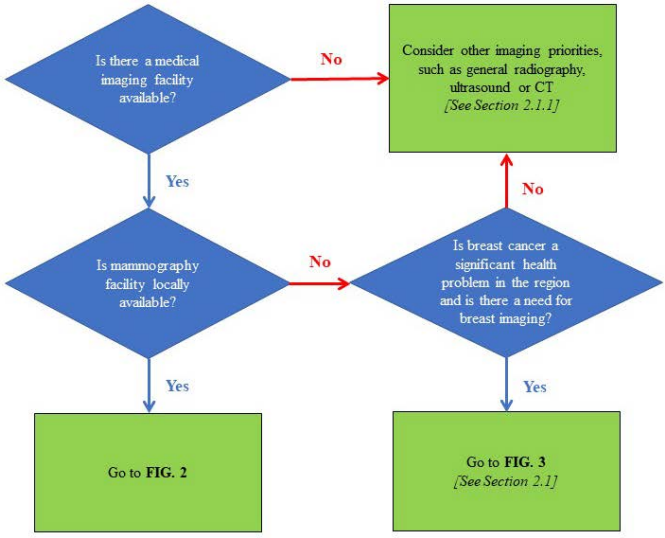

FIG. 1. Initial planning considerations for the implementation of mammography imaging.

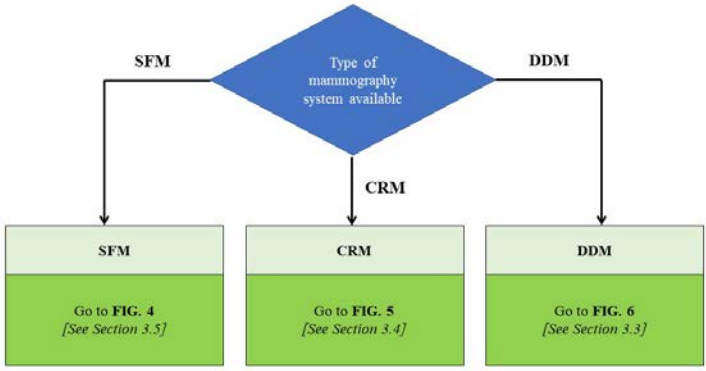

FIG. 2. Decision tree for facilities with established mammography imaging technologies.

such as appropriately trained radiologists, medical radiation technologists, CQMPs or service engineers. If there is an identified need for breast imaging, then implementation of a breast imaging facility can be recommended.

If screen-film general radiography is already being used in the facility, then a viable and realistic solution may be to consider initiating SFM. In addition to the need for purchasing an X ray mammography unit, however, dedicated cassettes, screens, films, mammography view boxes and a reading environment will be needed. A special processor will also be needed for developing mammography films. For chemical film processing, additional daily QC equipment and procedures will be required. Therefore, there are cost and time implications with the implementation of SFM. Furthermore, if no radiologist is available, it would also be necessary to transfer processed films to the location where the images would be reported. This could result in delays in obtaining a diagnosis. It may be more reasonable to initiate DDM in this scenario; or if adequate resources (for both purchase and maintenance) for DDM cannot be obtained, it is advisable to initiate CRM, although the latter is a less favourable choice than DDM.

In all cases, specialized training for the medical radiation technologists on patient positioning, breast compression, exposure and QC will be necessary. In such a facility, the mammograms would likely mainly be used for diagnostic purposes rather than for screening asymptomatic women. If there is a radiologist available on-site, special training in interpreting mammograms will be required. Otherwise, remote interpretation via tele-mammography could be considered. In any scenario, QC, dose and image quality optimization as well as patient dose assessment and review ought to be implemented and overseen by a CQMP.

Another solution, if appropriate, as part of a regional or national system, would be to consider participating in a mobile mammography programme

FIG. 3. Decision tree for determining the appropriate mammography imaging technology.

where a complete system, equipped with a DDM system and a trained medical radiation technologist, visits at regular intervals. Such a plan will also require a regular quality assurance programme (QAP) and optimization of practice for the equipment (see Section 4.4).

2.1.3. Hospital with an SFM facility

In this scenario, the case of a local or regional hospital with existing general radiology and SFM systems is discussed. The way forward depends greatly on

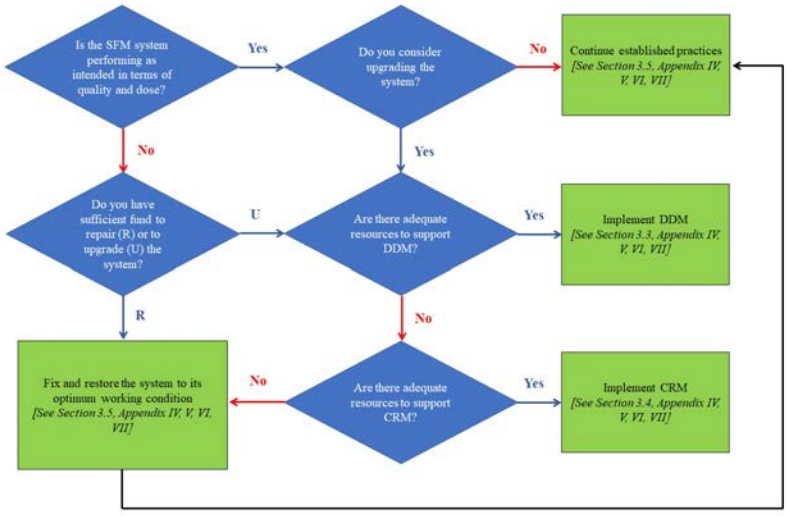

FIG. 4. Decision tree for a facility with SFM considering an upgrade.

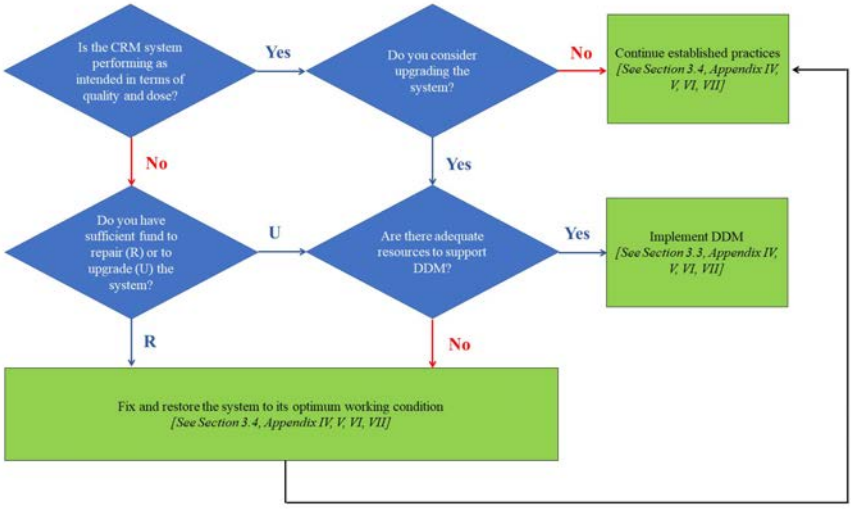

FIG. 5. Decision tree for a facility with CRM considering an upgrade.

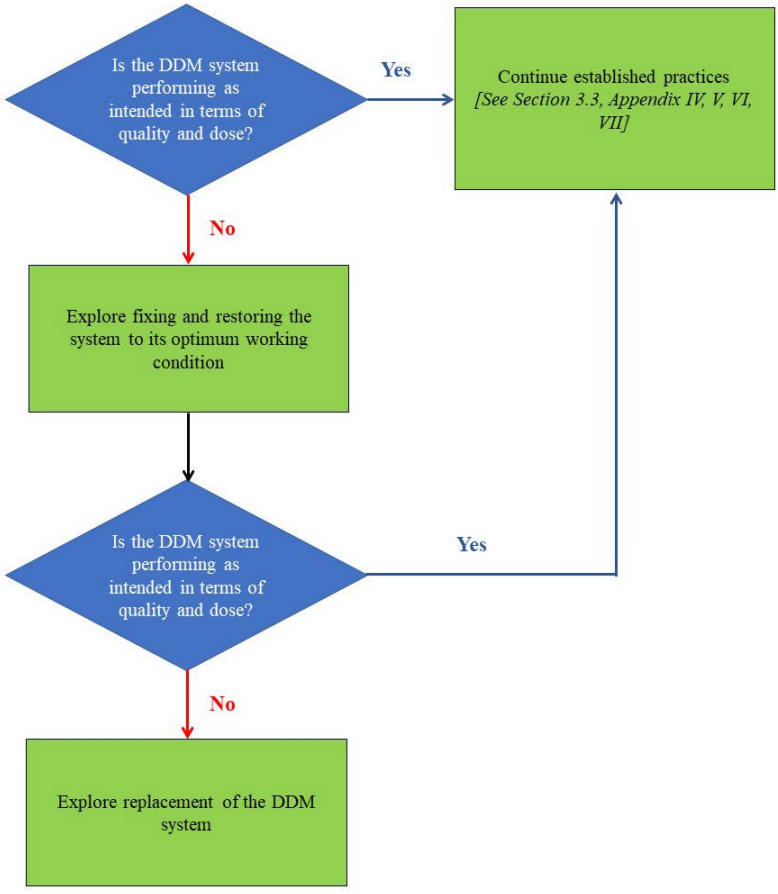

FIG. 6. Decision tree for facilities considering a change to their DDM.

the quality of imaging the facility currently achieves, the resources available and the volume of work performed at the facility.

If current mammographic imaging quality is compatible with recognized guidelines such as those of the American Association of Physicists in Medicine (AAPM) [10], American College of Radiology (ACR) [11], European Reference Organisation for Quality Assured Breast Screening and Diagnostic Services (EUREF) [6] or the IAEA [2, 5] and workload demands can be accommodated, then it is reasonable to continue with SFM. If it is planned to convert existing general radiography equipment to digital, then a conversion of mammography to either a CRM or DDM system could be considered. If the mammography machine is due for replacement, purchase of a DDM system or, if not feasible,

a CRM system, is recommended. It ought to be mentioned that retrofits for digital detectors and acquisition systems are now available at a lower cost than for a DDM system and may be a viable option; these are preferable to computed radiography (CR) plates [12]. It is essential in this case that the basic mammography unit (e.g. X ray tube and generator, gantry, compression, etc.) be in appropriate operating condition.

If the current quality of an SFM system is not adequate, this ought to ideally be addressed immediately. If image quality improvement is not possible or practical, a switch to DDM may be the solution.

2.1.4. Hospital with a CRM facility

For a local or regional hospital with existing general radiology and CRM systems, the way forward will depend greatly on the current quality of imaging achieved as well as the economic resources available and the volume of work performed at the facility. Different scenarios and justifications are elaborated below:

(a) The quality and efficiency of mammography could be improved by implementing DDM. If financial resources can be found, such a change is recommended.
(b) If the current quality of CRM is not adequate, this problem ought to ideally be addressed immediately. If it is not possible or practical (e.g. without major purchases) to make these improvements with CR plate technology, it is recommended that the facility consider switching to DDM as part of the solution to achieving high quality.
(c) If the current imaging quality is compatible with recognized guidelines such as those of the AAPM [10], ACR [11], EUREF [6] or the IAEA [2] and workload demands can be accommodated, then it is reasonable to continue with the existing CRM system. If the mammography equipment is due for replacement, purchase of a DDM system is recommended.

2.1.5. Tertiary care hospital with breast imaging

DDM is recommended in the case of a tertiary care hospital with a dedicated breast imaging service that includes multiple mammography units, several mammography medical radiation technologists, an adequate number of breast radiologists, and access to CQMPs and qualified service engineers. Although DDM systems can offer the highest quality images from a technical point of view, this quality is possible only if the DDM system is operating properly and

is being used correctly by appropriately trained personnel. Therefore, attention to QC and training standards is essential.

3. RESOURCES AND NEEDS

In this section, the resources and needs for different mammography technologies are described in detail.

3.1. PROJECT MANAGEMENT

Figure 7 shows the overall project management process in the establishment of a mammography facility. In developing the work plan, advice from a professionally trained radiologist, medical radiation technologist and CQMP, with experience in mammography, would be invaluable.

3.2. CORE CONSIDERATIONS

3.2.1. Needs analysis

Needs analysis is the first step in project management. The needs analysis ought to be carried out on the basis of existing demands as well as a realistic forecast. If an SFM is to be replaced by a DDM system, advice from experienced users would be useful. If local experience is not available, models from a similar health institution in the same country, or in a neighbouring country with similar socioeconomic structures, ought to be sought [8].

The following points ought to be considered during needs analysis:

— Clinical need for breast imaging. For example, breast cancer is a significant problem, or its incidence is increasing rapidly in the region.
— Available clinical infrastructure for diagnosis and treatment of breast cancers. This includes the access to means of pathological diagnosis and access to treatments.
— Appropriate expertise to perform mammography diagnosis and screening. There ought to be an adequate number of qualified radiologists and medical radiation technologists to carry out routine mammography services. If local

FIG. 7. Overall project management process to establish a mammography facility.

expertise (i.e. breast radiologist) is not available, telemammography may be considered.

— Financial resources to purchase the mammography equipment, support maintenance costs, replace expensive components at the end of their life and meet routine QC costs.

— Personnel to perform equipment maintenance, QC tests (daily tests by a medical radiation technologist and comprehensive tests by a CQMP) and professional advice and support from CQMP or information technology (IT) specialist.
— Expected patient volume or number of examinations per day.
— Possibility of lesion localization procedures.
— Possibility of advanced breast imaging techniques (e.g. tomosynthesis).
— Other breast imaging techniques (e.g. ultrasound) locally available.

3.2.2. Facility design

Once the needs analysis is completed and needs are clearly identified, then discussion on the design of the facility will be initiated. More specifically, the following items can be investigated:

— Physical space: Based on the examination volume and the mix of procedures, the required amount of equipment and rooms can be determined.
— Personnel: Based on the workload, this includes breast radiologists, medical radiation technologists, CQMPs and access to a qualified service engineer, administrative staff, IT support staff (if a digital system is chosen), etc.
— Workflow: The reception area, changing room, mammography equipment room, image processing area (e.g. darkroom for SFM, CR reader for CRM, digital workstation, etc.), image display and radiologist's reporting room, etc. ought to be located adjacent to each other for a better workflow. Supporting units such as IT and engineering services ought to be accessible or within the vicinity.
— Image and data management: Depending on the systems to be installed (SFM, CRM or DDM, either fixed or mobile), identify the storage requirements for images and data. Local regulations will dictate the minimum period of time they must be retained before they can be discarded. For digital data storage (cloud computing or a local server), it is necessary to comply with Health Level 7 standards.[1]
— Logistics: The mammography facility is usually located within an imaging department/centre so that the supporting services such as administration, scheduling, finance, etc. can be shared with other imaging services.

[1] http://www.hl7.org

3.2.3. Infrastructure and room

When planning any medical X ray imaging facility, it is necessary to ensure that nearby staff and public are not exposed to levels of radiation that exceed the current regulatory exposure limits [13].

A mammography room may be smaller in size than other X ray rooms because of the smaller dimensions of the equipment. The room shielding requirements are also reduced due to the low X ray energies used. Because of this, normal building materials such as gypsum wallboard may provide sufficient attenuation. However, if this approach is used, it is important to remember that recalculation of the shielding will be required if the room is used for other radiological purposes in the future [13]. Depending on the design of the equipment, techniques used and total workload, radiation shielding requirements ought to be properly calculated by qualified personnel such as CQMPs or radiation protection experts and approved by the regulatory bodies [13]. Details of the shielding calculation methods are described in Refs [14–17].

A typical mammography facility consists of the following structures (Fig. 8):

— Reception area;
— Waiting areas (at least one for casual clothing and the other for gowned individuals);
— Changing room(s) either inside or adjacent to the mammography equipment room;
— Equipment room large enough for the mammography system and acquisition computer workstation (if applicable) with private access for the patient and staff;
— Darkroom (for SFM) or space for a CR plate reader (if applicable) close to the mammography unit;
— Radiologists' interpretation and reading room with appropriate viewing conditions (e.g. low ambient light level);
— Space allocated to additional service needs, if possible, such as medical physics, IT and engineering equipment;
— Spaces for professional training and meetings, if possible, with appropriate technology including computers, software, Internet access, online resources, etc.

In addition, mammography equipment rooms require:

— Adequate power supply for uninterrupted function of the system without significant fluctuations. In all systems, an uninterruptable power supply (UPS) is recommended, while at least a simple surge protector ought to be

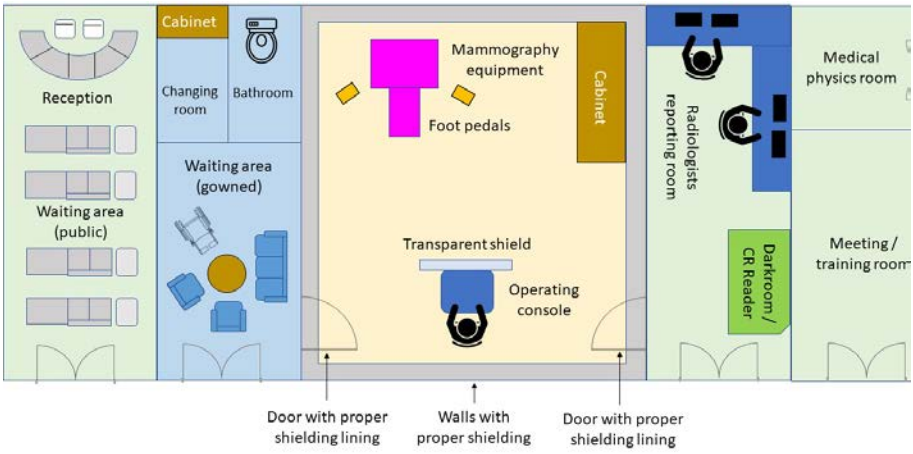

FIG. 8. Sample mammography facility layout.

added in the system when needed. Modern X ray generators can generally handle 5 second power outages, but not longer. Computers can be provided with a UPS, but normally the 10 to 30 minute range is the longest practical length of time for which these provide power.

— Temperature and humidity control to meet the needs of the imaging system. See the special needs of DDM systems in Section 3.3 both for image storage and operation.
— Dust control.
— Secure Internet access for software upgrades and possibly remote monitoring.
— Appropriate authorization (for the premises and the practices) according to the applicable legislation, which includes radiation protection.

3.2.4. Equipment

Equipment specifications need to be prepared by technical experts such as CQMPs, taking into consideration input from medical radiation technologists and radiologists, with full knowledge of the clinical needs and operational conditions, as well as regulatory requirements. Equipment specifications provided to the vendors ought to indicate the layout, the type of equipment/system needed, and the types of clinical procedures intended to be performed as well as a list of system components and description of the design, construction and performance features of each component. Any electrical, mechanical and environmental conditions which may affect the performance of the equipment ought to also be included [13, 18].

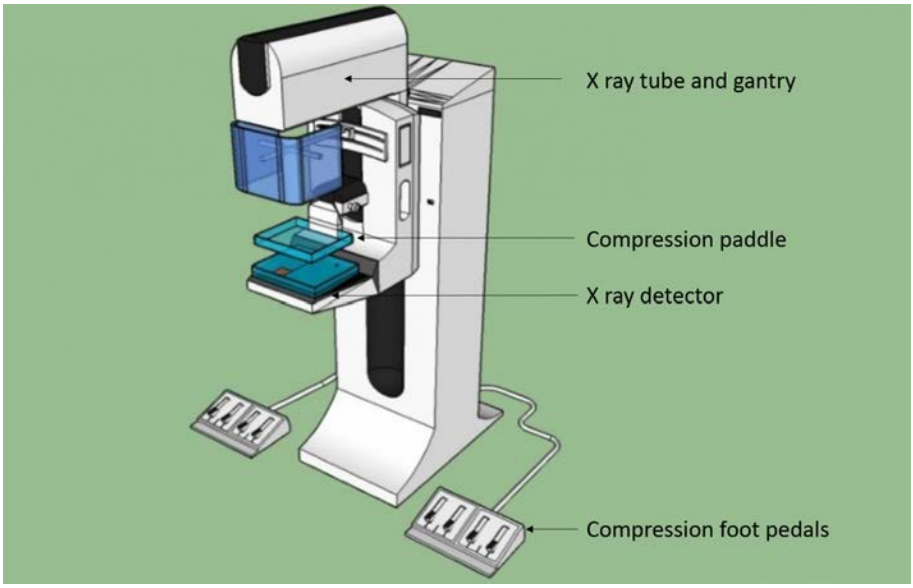

FIG. 9. Main components of typical mammography X ray equipment.

The main components of a mammography system (Fig. 9) include:

— X ray source (generator and tube) and gantry including compression paddle;
— X ray detector;
— Image processor (for an SFM or CRM system);
— Image display for interpretation;
— Data archive;
— Quality control tools and materials;
— UPS.

As the designs and characteristics of the equipment depend strongly on the type of technology used, these will be described in more detail in Sections 3.3–3.5.

3.2.5. Authorization needs

Once the initial needs analysis is completed and discussion of the facility design is initiated, the authorization needs ought to be identified. These need to follow local or national legislation and regulatory bodies' requirements. This involves at least authorization by the regulatory body for radiation protection and by the health authority to carry out clinical practice. The authorization for radiation protection may be a two stage process of an initial application to build

a facility (submitted before construction begins) followed by a full review and assessment by the regulatory body, leading to granting of authorization [13]. If the mammography system will be used for screening, additional justification and authorization might be needed.

3.2.6. Staff

Hiring and training of the dedicated staff to provide mammography services (including radiologists, medical radiation technologists and CQMPs) ought to be identified. In certain cases, when on-site staff cannot be available, access (e.g. through a contract) to adequate professional services is required. It is important to budget staff costs including training during the initial planning.

3.2.7. Staff training

It is considered necessary for all staff members to have the certification required by local or national legislation to practice in the field of mammography. More information on the elements of the training required for the imaging staff is discussed in Appendix VI. People with adequate training who are licensed to operate in a mammography facility ought to include the following staff:

— Radiologists;
— Medical radiation technologists;
— CQMPs;
— Administrative staff.

Continuing education is important for radiology professionals including those working in mammography. There are various methods (vendor videos, professional organizations, for-profit courses) to continually update knowledge in breast imaging. Most professional organizations recommend 15 hours of continuing education every three years, including the topic of radiation protection and medical exposure (justification and optimization).

3.2.8. Procurement

Once all of the above issues are addressed, then equipment procurement can be planned. Tender processes are usually applied in most centres to invite submission of quotations and technical specifications from multiple vendors. The specifications need to be thoroughly reviewed to ensure that the qualified vendors have addressed all the identified needs of the equipment and facility. The quotation ought to also include a fully comprehensive maintenance and service

contract, such as installation and calibration of the equipment, warrantees, delivery time, maintenance plans, QC tools, staff training and all other criteria as listed in the purchaser's specifications. A purchase contract that sets out all items and conditions of the purchase as agreed by both the purchaser and the assigned vendor is recommended. The contract ought to also include actions to be taken if conditions for acceptance are not met. A detailed and concise purchase contract will ensure the delivery of equipment in a timely and cost effective manner [18].

3.2.9. Site-specific training

The training of all related staff on-site is vital for the successful implementation of a mammography programme. This is particularly important for medical radiation technologists and radiologists. Plans for continuing education ought to also be identified. In developing the work plan, advice from professionally trained radiologists, medical radiation technologists and CQMPs with experience in mammography would be valuable.

The training programmes ought to include:

— Acceptance testing and commissioning of the equipment by a qualified CQMP;
— Implementation of a QAP;
— Breast screening and/or diagnostic workflow.

3.2.10. Quality

Every facility ought to develop and put in place a relevant QAP with the participation of all professionals involved under the supervision of a CQMP. This is explained in more detail in Appendix V, but in terms of major quality needs, the QAP ought to include the following:

(a) Preparation of relevant approval documents of the equipment for mammography use, as well as ensuring required approvals for electrical safety and radiation safety;
(b) An organized QAP compatible with international or national recommendations that includes:
    (i) Acceptance test performed by a CQMP, with system adjustments until the system passes all the required physico-technical tests.
    (ii) Approval of the clinical image quality by the radiologist team.
    (iii) Regular QC testing. Although it is very difficult to develop a technical QC test that correlates completely with clinical imaging performance, it is known that, to detect cancer, it is necessary to visualize subtle

changes in tissue for very small objects (e.g. microcalcifications) with a sufficiently high signal to noise ratio. It is desirable to do this at the lowest radiation dose compatible with such a task. There are various physical QC tests such as those developed and described as part of the programmes from the AAPM [10], EUREF [6], the European Federation of Organisations for Medical Physics [19] and the IAEA [2, 5]. Tests of this sort ought to be used as part of the QC. Details of the testing are discussed in Appendix V.

3.2.11. Maintenance

Every facility ought to assure that maintenance is provided at least yearly or in accordance with the recommendations of the manufacturer if that is more often [13]. Maintenance for the first year after purchase is normally included as part of the purchase price and is called a warranty. Maintenance packages for subsequent services can be purchased after the end of the warranty. It is important for the facility to determine at the time of purchase precisely what is and what is not covered by such packages, as the details can vary tremendously. It is possible that details of these packages are negotiable, but this is usually done before the facility commits to purchasing the equipment. There are very expensive components, such as the X ray tube, X ray detector and high resolution monitors. If the cost of replacing such components is not included in the package, then funds to cover replacement cost need to be secured. Having a maintenance package may also guarantee a faster response by the service group in repairing system problems. Maintenance ought to be done by qualified personnel trained by the manufacturer. The equipment logbook ought to also be kept up to date with all maintenance details and notes.

3.3. SPECIFIC NEEDS FOR DDM

The specific needs for a DDM facility are discussed in this section.

Figure 10 shows the typical workflow in a DDM facility. With the advantages of digital technology, the mammographic image and data can be viewed and analysed immediately once acquired, conveniently stored, printed and transmitted to the picture archiving and communication system (PACS).

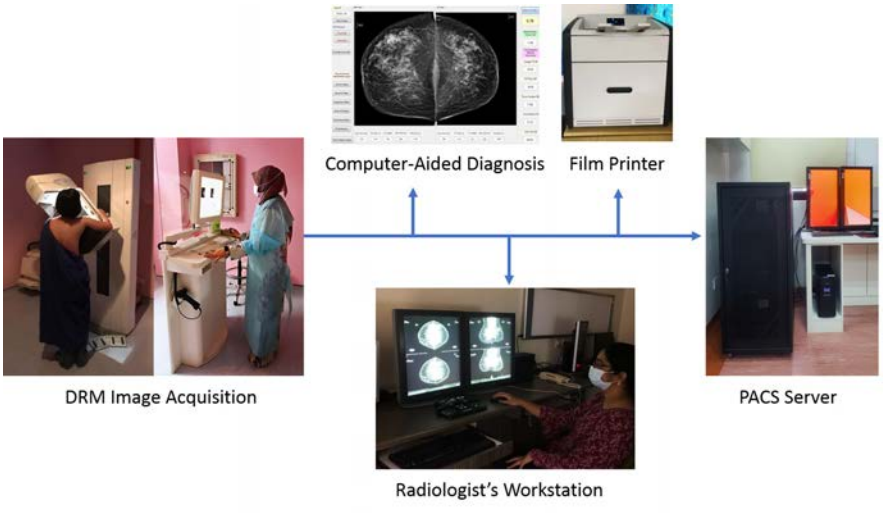

FIG. 10. Typical workflow in a DDM facility. Once the digital image is acquired, it can be shared instantly with the image processing software (e.g. computer aided diagnosis), radiologist's workstation and PACS server for evaluation. The image can either be stored digitally or printed in hard copy. (Images courtesy of Hospital Sungai Buloh, University of Malaya Medical Centre and Bin Zheng, Malaysia.)

3.3.1. DDM equipment

Importantly, all mammography equipment ought to comply with relevant standards for mammography [9] as minimum requirements to ensure suitability for clinical use. A clinical DDM system includes the following:

— X ray source (X ray generator and X ray tube);
— Digital detector;
— Acquisition workstation/operating console;
— UPS;
— Image processing and diagnosis workstation;
— Applicable software.

Table 1 shows the recommended minimum specifications for a modern DDM system. Optionally, the system could be upgradeable to one with contrast-enhanced digital mammography (CEDM) and digital breast tomosynthesis (DBT). Figure 11 shows the typical layout of a DDM equipment room while Fig. 12 illustrates the main components of DDM X ray equipment.

TABLE 1. RECOMMENDED MINIMUM SPECIFICATIONS FOR A MODERN DDM SYSTEM [2, 6, 11, 20–22]

X ray generator	
Power	≥5.0 kW
Tube voltage range	24–35 kVp (maximum 1 kVp step)
Tube load range	At least 5–400 mAs
AEC	Manual and automated selection of kVp, mAs, filter
Exposure time range	At least 30 ms to 2 s
Anode and filter material	Materials need to allow for low dose/high penetration spectra, even for thick or dense breasts. Examples of appropriate target materials are, for X rays: molybdenum (Mo), rhodium (Rh), tungsten (W) and for beam filter(s): Mo, Rh, aluminium (Al), silver (Ag)
Focal spot	Two (approximately 0.3 mm and 0.1 mm); with both manual and automated selection of the focal spot available
Anode heat capacity	At least 200 000 HU
X ray tube and gantry	
Collimators	Fully automated adjustment for different paddles, sizes and magnification
Movements	Motorized vertical and rotating movement
Arm locking system	Electromechanical brakes or equivalent
Arm moving system	Motorized
Control buttons for vertical and rotational movement	On both sides of C-arm
Focal spot to image detection distance (SID)	≥65 cm
Patient face shield	Provided for 2-D imaging

TABLE 1. RECOMMENDED MINIMUM SPECIFICATIONS FOR A MODERN DDM SYSTEM [2, 6, 11, 20–22] (cont.)

Breast compression	— Manual and automated breast compression — Maximum force when automated is between 150 N and 200 N — Emergency release — Automatic decompression after exposure
Digital numerical indicator, both sides	For C-arm rotation angle and compression force
Memorizable mediolateral oblique (MLO) angle	C-arm that can stop automatically at contralateral angle
Scatter rejection	Antiscatter grid (or equivalent technology)
Magnification views	— At least one magnification view (with magnification stand) — Magnification ratio provided, display provided
Antiscatter grid removal	Automatic, motorized for magnification views
Breast compression paddles	Several sizes (e.g. 18 cm × 24 cm and 24 cm × 30 cm) with small breast, spot and magnification paddles included
	Digital detector
Detector type	Preferably direct conversion flat panel detector (amorphous selenium (a-Se) or similar)
Effective field size	At least equivalent to 24 cm × 29 cm
Pixel size	≤100 μm
Dead pixel map	Provided
Image depth	At least 12 bit
System spatial resolution	≥7 lp/mm
	Acquisition workstation
General	A separate workstation for image positioning and patient demographic data

TABLE 1. RECOMMENDED MINIMUM SPECIFICATIONS FOR A MODERN DDM SYSTEM [2, 6, 11, 20–22] (cont.)

Operator controls	Both detector and generator controls integrated in the same console
Exposure parameters setting	Both manual and fully automatic
Standard clinical protocols	Documented on a chart and/or preprogrammed within the system
Computer system	Latest technology (processor generation/type/speed, RAM or operating memory, hard disk, storage systems, etc.)
Storage capacity	According to the facility's need (e.g. minimum 5000 patients, both projections, both breasts)
Monitor	At least 3 MP high resolution flat panel
Time between sequential acquisitions	<30 s
Time between acquisition and workstation preview	<15 s
Patient dose display and record	Dose indexes for each exposure need to be displayed and recorded
DICOM* functionality and connectivity	DICOM compatible (e.g. DICOM 3.0)
Image processing	Image analysis tools (e.g. mean, standard deviation, and region of interest tool with adjustable size and shape)
Additional capabilities	— Ability to perform repeat/reject analyses — Special processing for implants — Ability to add comments to an image
Hand/foot switches	Double hand switch for the exposure and double foot switch for breast compression/arm movements
Radiation protection barrier dimensions	Adequate to protect the operator (as calculated by the qualified personnel) Dimensions need to be provided.

TABLE 1. RECOMMENDED MINIMUM SPECIFICATIONS FOR A MODERN DDM SYSTEM [2, 6, 11, 20–22] (cont.)

Radiation protection barrier thickness	— Adequate thickness to protect the operator (as calculated by the qualified personnel) — Lead equivalence (mmPb) needs to be provided
Power supply	
UPS	Dedicated on-line UPS (for all workstations and accessories) for a minimum backup time of approximately 30 minutes
Image processing and diagnosis workstation	
Workstation	System of the latest technology workstation class hardware (processor generation/type/speed, RAM, hard disk, storage systems, etc.)
Monitors	At least two diagnostic mammography approved monitors of at least 5 MP and 53.5 cm (21 inches), with automated self-calibration
Display graphic card	High end medical grade
Storage capacity	As required (e.g. at least 1.5 Terabyte (TB))
Workstation capabilities	— Display of multiple images and priors for comparison purposes Multimodality viewer capability for display of ultrasound, X ray, digital mammography, MRI, PET, CT on a third colour monitor
Mouse, keypad	Dedicated keypad for mammography, common keypad, mouse
Software and interconnectivity	

TABLE 1. RECOMMENDED MINIMUM SPECIFICATIONS FOR A MODERN DDM SYSTEM [2, 6, 11, 20–22] (cont.)

Software	Dedicated breast imaging software with at least the following functions: — Magnification — Zoom — Pan — Windowing — Brightness adjustment — Contrast adjustment — Distance measurement — Histogram display — Contrast enhancement
Display capabilities	One-to-one image display: One pixel on detector corresponding to one pixel on monitor
Interconnectivity	— Full DICOM compatibility (e.g. DICOM 3.0) — Media export/import — Automated transfer of the image acquisition parameters (e.g. kV, mAs, target and filter material, breast thickness, compression force, projection, L/R) for each exposure into the DICOM header Capability to export unprocessed and processed DICOM images

***** DICOM: digital imaging and communications in medicine.

3.3.2. Review workstation

Ideally, digital images will be interpreted on a display station with two high resolution monitors (at least 5 MP) or one 8 MP medical grade monitor. Side by side viewing is required during image reading, for left versus right breast, MLO versus craniocaudal views or current versus previous exams. If it is not possible to purchase two monitors, software ought to be available to allow side by side viewing of images on a single high resolution monitor. Dedicated image 'hanging' (display) protocols ought to be available to allow the above comparisons. The monitors ought to be calibrated according to the Grayscale Standard Display Function [23–25].

In addition, workstations (Fig. 13) or the PACS ought to be equipped with software to manage workflow and standard postprocessing functions as well as having window level control for manual adjustment of the display conditions.

FIG. 11. Typical layout of a DDM imaging room. (Photo courtesy of University of Malaya Medical Centre, Malaysia.)

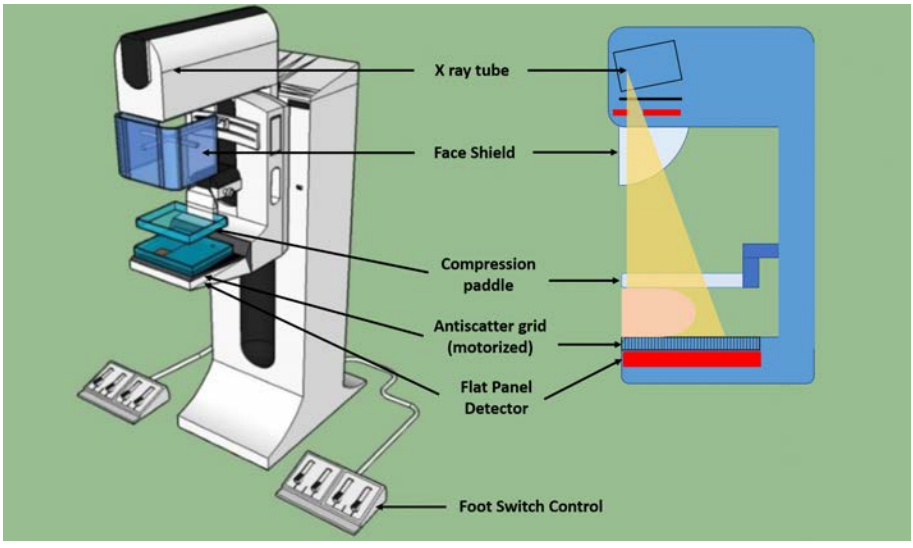

FIG. 12. Main components of DDM X ray equipment.

FIG. 13. Example of a reporting workstation that is equipped with PACS and postprocessing software. (Photo courtesy of University of Malaya Medical Centre, Malaysia.)

The workstations or PACS ought to be able to import and display mammograms (such as previous images of the same patient and those acquired at other facilities) as well as to export images in a form accessible to external viewers (such as surgeons, oncologists, for second opinions, etc.). Planned periodical QC ought to be performed on the workstation(s) and viewing monitors.

3.3.3. Data archiving

Ideally, the system will be connected to a PACS system in the facility. Otherwise, some other form of digital storage is required that is appropriate to the workload of the facility. Approximately 40 MB is required for each DDM examination, assuming lossless compression.

3.3.4. Image printing

Ideally, image interpretation will be done on a workstation with high resolution monitors (i.e. 'soft copy viewing') so that the image can be manipulated

FIG. 14. (a) Hard copy image can be printed using a laser printer and imaging film. (b) A properly calibrated view box is required to view the hard copy film. (Photo courtesy of Konstantopoulio General Hospital, Greece.)

interactively while viewing. If this is not feasible, a less desirable option is to print images on a high resolution printer ('hard copy viewing') (Fig. 14). This ought to be done at full size (1:1, one pixel printed for one pixel in the image) so that information is not lost, and the printer ought to be calibrated to provide appropriate greyscale rendition.

If interpretation is done from films or if film mammograms obtained from other facilities or from previous examinations at this facility are to be used for interpretation or comparison purposes, an appropriate mammography film viewer (view box) is required for reviewing the images.

3.3.5. Environmental requirements

Detectors for DDM systems are temperature sensitive, and each manufacturer has specified acceptable ranges for both temperature and humidity for the transportation, idle conditions and operating conditions of its detector system. Detectors are generally delivered separately from the rest of the X ray device and are maintained under appropriate environmental conditions during shipping. Once the system has been installed, environmental conditions need to be acceptable both under conditions of operation and when the system is not in use (e.g. during holidays or repair activities).

3.3.6. Quality

The general quality requirements are as stated in Section 3.2.10, with the following additional considerations:

— A comprehensive QAP for DDM systems ought to be in place, as described in international guidelines [2, 6, 7].
— Test objects, software tools and dosimetry equipment ought to be available for QC of the DDM system. It is recommended that those tools be included in the procurement plan of new installations to minimize or optimize costs and avoid subsequent unanticipated expenses.

3.3.7. Maintenance

Annual equipment checks ought to be done by a service engineer to ensure consistent and reliable performance of the system. In addition to the standard maintenance of a mammography system, regular detector calibration is needed for each digital detector by manufacturers. The calibration ought to be performed at least quarterly. Maintenance ought to be carried out by qualified personnel trained by the manufacturer. Maintenance logbooks ought to be kept up to date.

3.3.8. Staff training

Transition from an SFM to a DDM is a challenging task that requires additional competencies for all involved professionals. Some of the required additional skills for radiologists, medical radiation technologists and CQMPs are shown in Table 2.

3.4. SPECIFIC NEEDS FOR CRM

The CRM systems, if used optimally, can achieve nearly the same image quality as DDM systems, although spatial resolution is typically not as good, and a higher radiation dose is required [26, 27]. It is also more labour intensive than DDM, as cassettes are transferred from the mammography unit to the reader, and the reading is not instantaneous. The capital cost of a CRM system is lower than that of a DDM system, and if there is an existing SFM system on-site and in good condition, it may be possible to convert it to a CRM unit with appropriate CR plates.

Figure 15 shows the typical workflow of a CRM facility.

TABLE 2. ADDITIONAL DDM SKILLS REQUIRED FOR A RADIOLOGIST, MEDICAL RADIATION TECHNOLOGIST AND CQMP

Personnel	Additional skills
Radiologist	— Basic principles of digital mammography — Basic understanding on the modality and technique — Reading/reviewing with the new modality (or telemammography) — Basic computer skills especially related to digital image postprocessing — Adapting to the different, possibly unfamiliar appearance of digital images — Judging clinical image quality — In-depth teaching on-site in the optimal use of the modality, including image presentation, storage and retrieval (to and from PACS and other media) — Basics of DICOM and PACS — Digital image windowing — How to evaluate quality (i.e. images acquired by medical radiation technologists, image processing and QC tests by the CQMPs) — Use of additional features, if available (computer aided detection, DBT, contrast-enhanced imaging, etc.) — Creating databases, especially for teaching purposes, if applicable
Medical radiation technologist	— Basic principles of digital mammography — Basic understanding of the modality and technical specifications — Positioning and compression for breast imaging (including training specific to the system, e.g. DBT, magnification, spot compression view, mammographic-guided biopsy, etc.) — In-depth training on optimal use, including image presentation, storage and retrieval (to and from PACS and other media), DICOM knowledge, AEC functions, image windowing, etc. — Computer skills — New QA/QC procedures, including identification of artefacts from both QC and patient images — Routine detector calibration — Interpretation of dose index display and their registration
CQMP	— Physical principles of digital mammography — Advanced knowledge on the technical specifications — Quality assurance protocols and interpretation — In-depth knowledge in image quality and dose optimization — Advanced computer skills (in handling DICOM images) — Knowledge of basic image processing — Basics of networking (to support PACS)

FIG. 15. Typical workflow in a CRM facility: (a) Patient is registered by scanning the barcode on the CR imaging plate/cassette. (b) The imaging plate/cassette is inserted into the cassette holder of the mammography equipment. (c) Once X ray acquisition is done, the cassette is removed from the mammography equipment and processed under a CR reader. (d) Digital image appears on the computer system once the reading is done. Radiologists can view and perform postprocessing on the digital image, if needed. (e) The image can also be printed in hard copy using a laser printer or laser imager for film. (f) The printed image can be viewed using a calibrated view box. (Photo courtesy of Konstantopoulio General Hospital, Greece.)

3.4.1. CRM equipment

All equipment complies with relevant standards for mammography equipment (e.g. IEC [9]) as a minimum requirement to ensure suitability for clinical use. A clinical CRM system includes the following:

— X ray source (X ray generator and X ray tube);
— Acquisition workstation/operating console;
— Cassette-based imaging plates;
— UPS;
— Computed radiography reader;
— Image processing and diagnosis workstation;
— Various software.

Table 3 shows the recommended specifications for a CRM system.

TABLE 3. RECOMMENDED MINIMUM SPECIFICATIONS FOR A CRM SYSTEM [2, 28, 29]

	X ray generator
Power	≥5.0 kW
Tube voltage range	24–35 kVp (maximum 1 kVp step)
Tube load range	At least 5–400 mAs
AEC	Manual and automated selection of kVp, mAs, filter
AEC sensor (phototimer)	Located underneath the screen-film cassette with adjustable position below appropriate region of the breast
Exposure time range	At least 30 ms to 2 s
Anode and filter material	Appropriate material(s) for X ray target (e.g. Mo, Rh, W) and beam filter(s) (e.g. Mo, Rh, Al, Ag)
Focal spot	Two: approximately 0.3 mm usually used for contact mammography and 0.1 mm primarily used for magnification
Anode heat capacity	At least 200 000 HU
	X ray tube and gantry
Collimators	Fully automated adjustment for different paddles, sizes and magnification
Movements	Motorized vertical and rotating movement
Arm locking system	Electromechanical brakes or equivalent
Arm moving system	Motorized
Control buttons for vertical and rotational movement	On both sides of C-arm
Focal spot to image detection distance (SID)	>60 cm

TABLE 3. RECOMMENDED MINIMUM SPECIFICATIONS FOR A CRM SYSTEM [2, 28, 29] (cont.)

Patient face shield	Provided
Breast compression	— Manual and automated breast compression — Maximum automated force between 150 N and 200 N — Emergency release — Automatic decompression after exposure
Digital numerical both sides indicator	For C-arm rotation angle and compression force
Memorizable MLO angle	C-arm that can stop automatically at a contralateral angle
Scatter rejection	Antiscatter grid (or equivalent technology)
Magnification views	At least one magnification view (with magnification stand) as specified; magnification ratio needs to be provided
Antiscatter grid removal	Automatic, motorized for magnification views
Breast compression paddles	Several sizes available (e.g. 18 cm × 24 cm and 24 cm × 30 cm) with small breast, spot and magnification paddles included
Cassette holder and bucky	Available to hold different cassette sizes (i.e. 18 cm × 24 cm and 24 cm × 30 cm) and a large bucky if appropriate to the population
Acquisition workstation	
General	A separate workstation for image positioning and patient demographic data
Operator controls	Generator controls integrated in the same console
Exposure parameters setting	Both manual and fully automatic
Standard clinical protocols	Documented on a chart and/or preprogrammed within the system

TABLE 3. RECOMMENDED MINIMUM SPECIFICATIONS FOR A CRM SYSTEM [2, 28, 29] (cont.)

Computer system	Latest technology (processor generation/type/speed, RAM, hard disk, storage systems, etc.)
Storage capacity	According to the facility's needs (e.g. minimum 5000 patients, both projections, both breasts)
Monitor	At least 3 MP high resolution flat panel
DICOM functionality and connectivity	DICOM compatible (e.g. DICOM 3.0)
Image processing	Image analysis tools (e.g. mean, standard deviation, and region of interest tool with adjustable size and shape)
Additional capabilities	— Ability to perform repeat/reject analyses — Special processing for implants — Ability to add comments to an image
Hand/foot switches	Double hand switch for the exposure and double foot switch for breast compression/arm movements
Radiation protection barrier dimensions	Adequate for operator protection (as calculated by the qualified personnel) Dimensions need to be provided
Radiation protection barrier thickness	— Adequate thickness to protect the operator (as calculated by the qualified personnel) — Lead equivalence (mmPb) needs to be provided
Computed radiography detector (imaging plate)	
Detector type	Reusable photostimulable storage phosphor imaging plate stored in a cassette
Effective field size	Commonly available in two sizes:18 cm × 24 cm and 24 cm × 30 cm
Pixel size	≤50 μm
Image depth	At least 12 bit

TABLE 3. RECOMMENDED MINIMUM SPECIFICATIONS FOR A CRM SYSTEM [2, 28, 29] (cont.)

System spatial resolution	≥10 lp/mm
Number of imaging plate recommended	At least two of each size; preferably at least four of each size
Computed radiography reader	
Laser spot size	— 50 μm (modern reader) — 100 μm (conventional reader)
Readout time	— 50 s for a 18 cm × 24 cm imaging plate — 60 s for a 24 cm × 30 cm imaging plate
Transition time for digital image to be displayed on the workstation	30–60 s
Erasure time	10–20 s
Total cycle time (insert, read, remove and insert next cassette)	60–90 s (depending on the imaging plate size and signal density on the plate)
Image processing and diagnosis workstation	
Workstation	System of the latest technology workstation class hardware (processor generation/type/speed, RAM, hard disk, storage systems, etc.)
Monitors	At least two approved diagnostic mammography monitors of at least 5 MP and 53.5 cm (21 inches), with automated self-calibration
Display graphic card	High end medical grade
Storage capacity	As required (e.g. at least 1.5 TB)
Workstation capabilities	— Display of multiple images and priors for comparison purposes Multimodality viewer capability for display of ultrasound, X ray, digital mammography, MRI, PET, CT on a third colour monitor

TABLE 3. RECOMMENDED MINIMUM SPECIFICATIONS FOR A CRM SYSTEM [2, 28, 29] (cont.)

Mouse, keypad	Dedicated keypad for mammography, common keypad, mouse
Software and interconnectivity	
Software	Dedicated breast imaging software with at least the following functions: — Magnification — Zoom — Pan — Windowing — Brightness adjustment — Contrast adjustment — Distance measurement — Histogram display — Contrast enhancement
Display capabilities	One-to-one image display: One pixel on detector corresponding to one pixel on monitor
Interconnectivity	— Full DICOM compatibility (e.g. DICOM 3.0); — Media export/import — Automated transfer of the image acquisition parameters (e.g. kV, target and filter material, breast thickness, compression force, projection, L/R) for each exposure into the DICOM header — Capability to export unprocessed and processed DICOM images
Power supply	
UPS	Dedicated on-line UPS (for all workstations and accessories) for a minimum backup time of approximately 30 minutes

Figure 16 shows the main components in a CRM equipment room and Fig. 17 illustrates the structure of a CRM cassette/imaging plate.

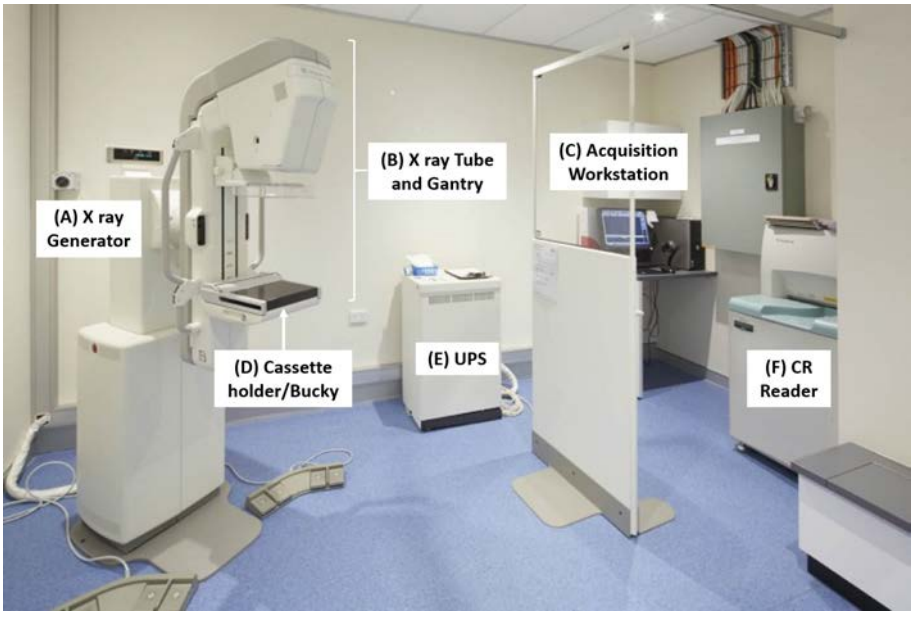

FIG. 16. Typical layout of a CRM equipment room. (Image courtesy of CPD Projects, Australia.)

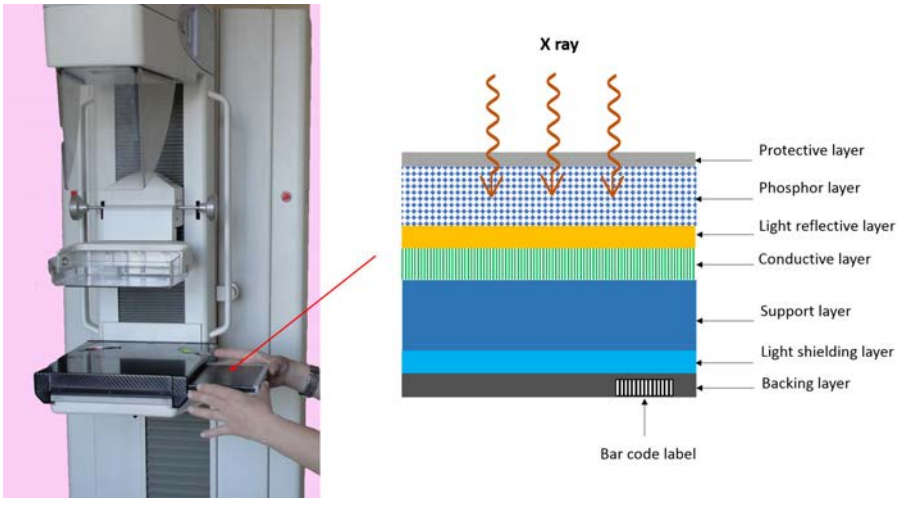

FIG. 17. Inner structure of a mammography CR cassette.

FIG. 18. Samples CR readers: (a) tabletop; (b) single slot; and (c) multiple slots.

3.4.2. Computed radiography reader

The CR reader can be used exclusively for mammography imaging plates or can be shared with other radiography plates. Ideally it needs to be optimized for mammography use with the specific imaging plate technology that is present. The readers are available in different designs (Fig. 18) to suit the local needs.

The reader needs to be equipped with a computer and a display to register the patient, identify the plate and review or check the image. It ought to be capable of dedicated image processing for a breast and of producing DICOM compatible image formats. It is desirable for technical data such as exposure parameters, compression force and mean glandular dose (MGD) to be automatically transferred to the appropriate tags in the DICOM header to allow tracking. Alternatively, these can be manually registered, although this can be time consuming.

The reader needs to be connected to PACS or to another storage device, whereby it ought to permit the export of images to other digital media, and appropriate software licences to do this need to be in place. It ought to be possible to export DICOM 'for processing images' for QC purposes too.

3.4.3. Review workstation

The review workstation requirements for a CRM facility are in general similar to those of a DDM [2]. Also in CRM, two high resolution monitors of at least 5 MP are required. If it is not possible to purchase two monitors, software ought to be available to allow side by side viewing of images on a single high

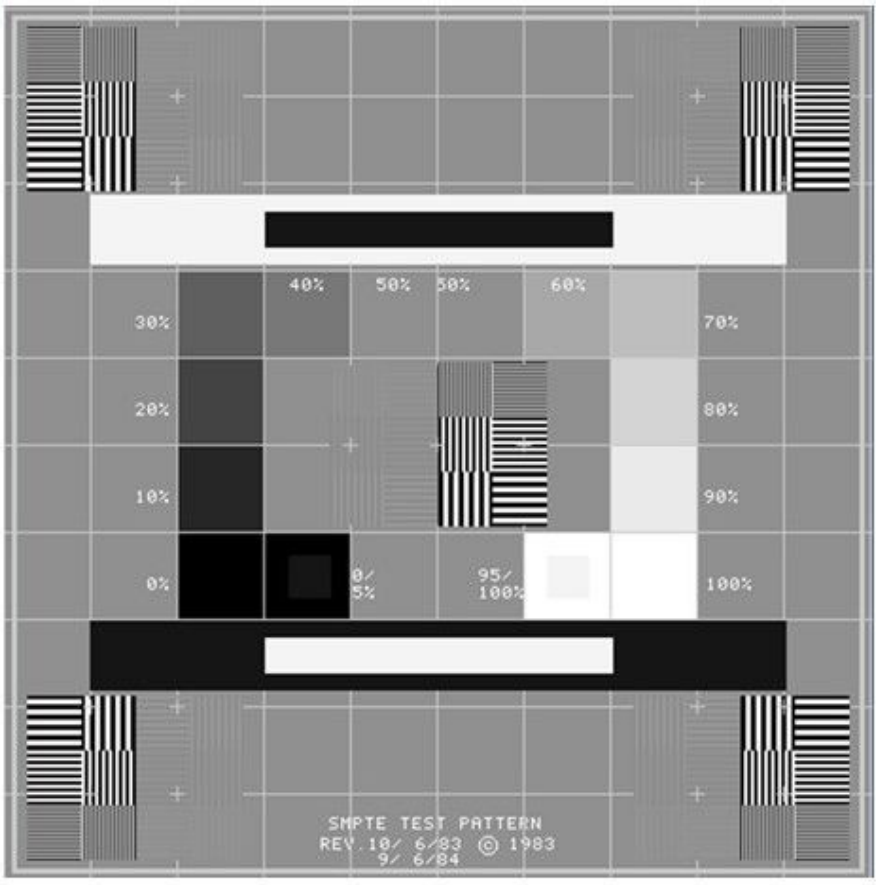

FIG. 19. Standardized Society of Motion Picture and Television Engineers test pattern, one type of test pattern that may be provided with the medical diagnostic monitor for quality control.

resolution monitor. As with DDM, the monitor(s) are calibrated according to the Grayscale Standard Display Function and tested regularly [2, 25] using the standard Society of Motion Picture and Television Engineers test pattern (Fig. 19) [25].

3.4.4. Data archiving

Ideally, the system will be connected to a PACS system in the facility. Otherwise, some other form of adequate digital storage is required that is appropriate for the workload of the facility. Approximately 40 MB is required for each examination that uses CR plates, assuming lossless compression.

3.4.5. Image printing

Ideally, image interpretation will be done on a workstation with high resolution monitors so that the image can be manipulated interactively while viewing. If this is not feasible, images can be printed on a high resolution film printer. This ought to be done at full size (1:1, one pixel printed for one pixel in the image) so that information is not lost. If interpretation is done from films (printed images), suitable film viewers (view boxes) are required.

3.4.6. Quality

The quality needs are as stated in Section 3.2.10, with the following additions:

— A comprehensive QAP for CRM needs to be in place, as described in international guidelines [2, 6, 7].
— Test objects, software tools and dosimetry equipment ought to be available for QC of the CRM system. It is recommended to include such equipment in the procurement plan of new installations to minimize or optimize costs and avoid subsequent unanticipated expenses.
— System optimization to detect small, subtle structures in the breast. Because CRM is less dose efficient than DDM, the main task is to get the best performance it can deliver. This is often quantified by achieving at least a specified value of the signal difference to noise ratio (SDNR) as a ratio to dose.

3.4.7. Maintenance

Although CR plates are part of the digital imaging component of the system, they are considered consumables and they need to be replaced when their performance is suspected to have deteriorated below set quality limits. This is a cost that needs to be foreseen in the planning of new practices and will depend on the workload of the department. The lifespan of a CR plate is typically hundreds or thousands of exposure–readout–erase cycles, determined primarily by the care in handling and environmental conditions. During their lifespan it is important that the CR cassettes and screens be kept in good working condition, and one staff member (usually the medical radiation technologist) ought to have the responsibility for their regular maintenance, such as cleaning, removing from service and requesting replacement of those cassettes that have degraded or cannot be cleaned. Maintenance ought to be done by personnel qualified and trained by the manufacturer. Maintenance logbooks need to be kept up to date.

3.4.8. Staff training

Transition from film to CRM is a challenging task and requires adequate competencies for all involved professionals. Some of the required additional skills for radiologists, medical radiation technologists and CQMPs are shown in Table 4.

TABLE 4. ADDITIONAL SKILLS REQUIRED IN CRM FOR A RADIOLOGIST, MEDICAL RADIATION TECHNOLOGIST AND CQMP

Personnel	Additional skills
Radiologist	— Basic principles of CRM — Basic understanding of the modality and technique — Reading/reviewing the modality (or telemammography) — Basic computer skills especially related to digital image postprocessing — Accommodation to the different, possibly unfamiliar appearance of digital images — Judgement of clinical image quality — In-depth training on optimal use of the modality, including image presentation, storage and retrieval (to and from PACS and other media) — Basics of DICOM and PACS — Image windowing — How to evaluate quality (i.e. images acquired by medical radiation technologists, image processing and QC tests by the CQMPs) — Use of additional features, if available (computer aided detection, etc.) — Creation of databases, especially for teaching purposes, if applicable
Medical radiation technologist	— Basic principles of CRM — Basic understanding of the modality and technical specifications — Positioning and compression for breast imaging (including training specific to CRM, e.g. when using new plate sizes) — In-depth training on optimal use of the modality, including image presentation, storage and retrieval (to and from PACS and other media), DICOM knowledge, AEC functionality, image windowing, dose indexes interpretation and recording, etc. — Computer skills — New QA/QC procedures, including identification of artefacts from both QC and patient images — Cleaning and handling of the CR image plates

TABLE 4. ADDITIONAL SKILLS REQUIRED IN CRM FOR A RADIOLOGIST, MEDICAL RADIATION TECHNOLOGIST AND CQMP (cont.)

Personnel	Additional skills
CQMP	— Physical principles of CRM — Advanced knowledge on the technical specifications of the modality — Quality assurance protocols and interpretation for CRM — In-depth knowledge of image quality and dose optimization in CRM — Advanced computer skills (in handling DICOM images) — Knowledge of basic image processing — Basics of networking (to support PACS)

3.5. SPECIFIC NEEDS FOR AN SFM

An SFM can provide excellent image quality, but quality tends to be reduced for dense breasts. In addition, it provides less flexibility than DDM or CRM, and image quality can be lower than DDM in the case of suboptimal film processing. There are challenges and cost implications associated with the acquisition and storage of film as well as the use and disposal of chemicals. Figure 20 shows the typical workflow of an SFM facility. Multiple steps and lengthy processes are involved to acquire, process, view and store an X ray film. As well, many of the costs, expertise needs, QC and QA activities would be centralized.

3.5.1. SFM equipment

All equipment complies with relevant standards for mammography equipment (e.g. IEC [9]) at minimum, to ensure suitability for clinical use. A clinical SFM system would ideally include the following:

— X ray source (X ray generator and X ray tube);
— Acquisition/operating console;
— Screen-film combination image receptor (Fig. 21);
— Darkroom for film processing (Fig. 22);
— Film viewing and display room.

Table 5 shows the recommended specifications for an SFM system.

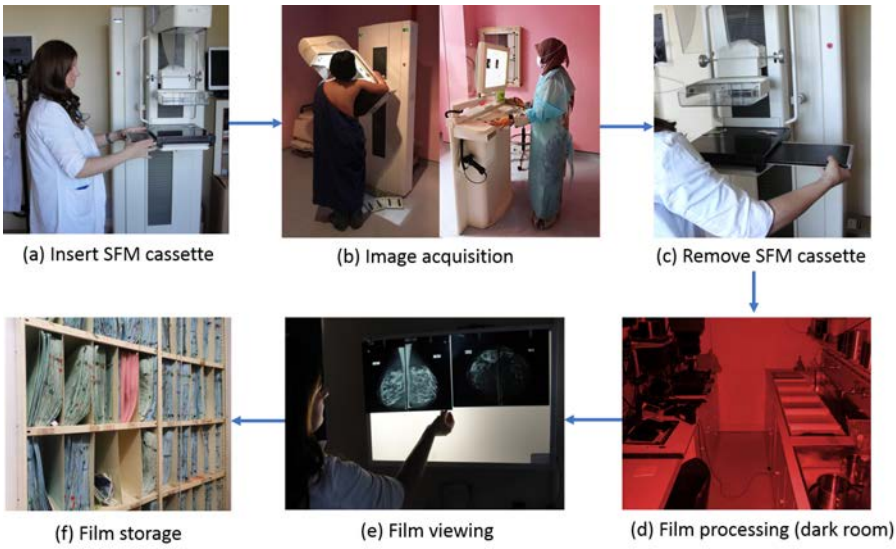

FIG. 20. Typical workflow in an SFM facility. (Images courtesy of Konstatopoulio General Hospital, Greece and Hospital Sungai Buloh, University of Malaya Medical Centre, Malaysia.)

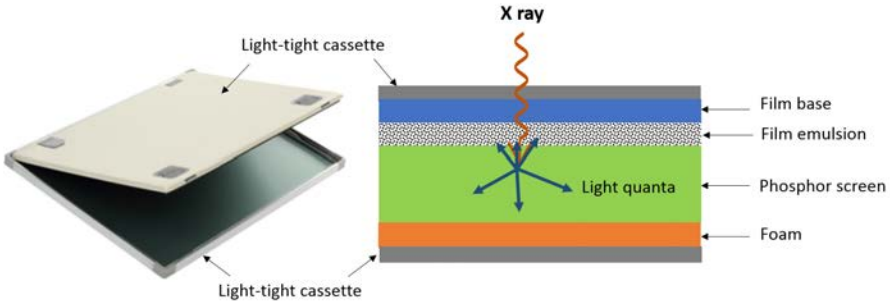

FIG. 21. Construction of a mammography screen-film system (single-emulsion single-screen combination).

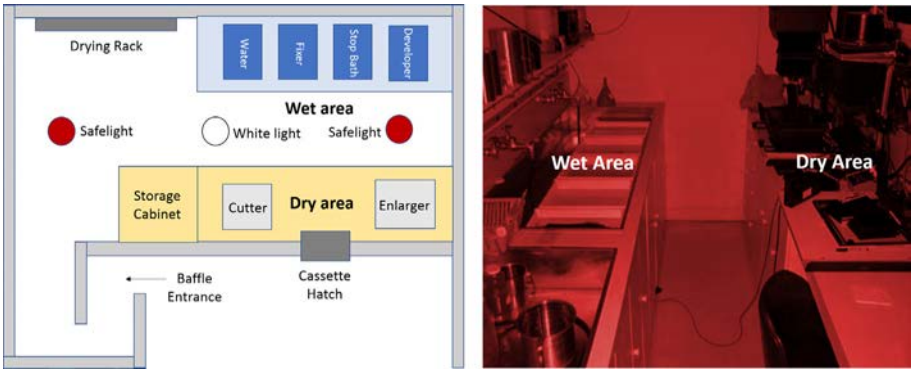

FIG. 22. Typical darkroom layout. (Image courtesy of Chan Lai Kuan, Malaysia.)

TABLE 5. RECOMMENDED MINIMUM SPECIFICATIONS FOR AN SFM SYSTEM [5, 6, 28, 30–32]

X ray generator	
Power	≥5.0 kW
Tube voltage range	24–35 kVp (maximum 1 kVp step)
Tube load range	At least 5–400 mAs
AEC	Manual and automated selection of kVp, mAs, filter
AEC sensor (phototimer)	Located underneath the screen-film cassette, with position adjustable below appropriate region of the breast
Exposure time range	At least 30 ms to 2 s
Anode and filter material	Appropriate target material(s) for X ray (e.g. Mo, Rh, W) and beam filter(s) (e.g. Mo, Rh, Al, Ag)
Focal spot	Two: approximately 0.3 mm usually used for contact mammography and 0.1 mm primarily used for magnification
Anode heat capacity	At least 200 000 HU
X ray tube and gantry	

TABLE 5. RECOMMENDED MINIMUM SPECIFICATIONS FOR AN SFM SYSTEM [5, 6, 28, 30–32] (cont.)

Collimators	Fully automated adjustment for different paddles, sizes and magnification
Movements	Motorized vertical and rotating movement
Arm locking system	Electromechanical brakes or equivalent
Arm moving system	Motorized
Control buttons for vertical and rotational movement	On both sides of C-arm
Focal spot to image detection distance (SID)	≥60 cm
Patient face shield	Provided
Breast compression	— Manual and automated breast compression — Maximum automated force between 150 N and 200 N — Emergency release — Automatic decompression after exposure
Memorizable MLO angle	C-arm that can stop automatically at a contralateral angle
Magnification views	At least one magnification view (with magnification stand). Magnification ratio needs to be provided
Antiscatter grid	Moving antiscatter grid with grid ratio between 3.5:1 and 5:1, for each image receptor size that is removable for magnifications views
Breast compression paddles	Available in different sizes (i.e. 18 cm × 24 cm and 24 cm × 30 cm). Small breast, spot and magnification paddles need to also be included
Film cassette holder and bucky	Available to hold different cassette sizes (e.g. 18 cm × 24 cm and 24 cm × 30 cm) and a large bucky if appropriate to the population
Operating console	

TABLE 5. RECOMMENDED MINIMUM SPECIFICATIONS FOR AN SFM SYSTEM [5, 6, 28, 30–32] (cont.)

General	A separate workstation for image positioning and patient demographic data is required
Operator controls	Generator controls integrated in the same console
Exposure parameters setting	Both manual and fully automatic
Standard clinical protocols	Documented on a chart and/or preprogrammed within the system
Hand/foot switches	Double hand switch for the exposure and double foot switch for breast compression/arm movements
Radiation protection barrier dimensions	Adequate for operator protection (as calculated by the qualified personnel) Dimensions need to be provided
Radiation protection barrier thickness	— Adequate thickness to protect the operator (as calculated by the qualified personnel) — Lead equivalence (mmPb) needs to be provided
	Screen-film image receptor
Detector type	Single back intensifying screens used with single-emulsion radiographic film enclosed in a lightproof cassette. All cassettes used in the department need to be identical
Intensifying screen	Commonly available in two sizes: 18 cm × 24 cm and 24 cm × 30 cm (paired with the mammographic films)
Quantum detection efficiency	~60% for a typical screen thickness and X ray spectrum
X ray to light conversion efficiency	>10%
Mammographic film type	Films need to be of the same type (manufacturer, sensitivity rating, etc.) and be compatible with the phosphor screens and cassettes

TABLE 5. RECOMMENDED MINIMUM SPECIFICATIONS FOR AN SFM SYSTEM [5, 6, 28, 30–32] (cont.)

Film size	18 cm × 24 cm and 24 cm × 30 cm (compatible with the phosphor screen and cassette)
Film emulsion	Matched to be sensitive to the spectrum of light emitted from the phosphor screen
Target optical density	1.5–1.9
Film sensitivity (speed)	Compatible with the phosphor screen
Screen-film combination speed	Relative speed 150–200
System spatial resolution	≥11 lp/mm
	Darkroom for film processing [5]
Location	Adjacent to the mammography room
Background radiation	Acceptable level is <20 μGy/week
Work surface	Made of hard, antistatic material that is easily cleaned at least 1.3 m long for the loading and unloading of cassettes
Entrance	Absolute light-tight door or baffle entrance is recommended
Lighting	Two levels of lighting: a strong white light when film processing is not in progress and an exposure safe red light when processing is in progress. For safe light, the recommended bulbs are 15 W for direct safe lighting and 25 W if the safe lighting is not direct
Safe light filters	Absorption gelatine designed for a high degree of illumination and consistency for safe handling of photosensitive materials. Colour of the safe light filter is critical. It needs to be one to which films are least sensitive (e.g. when using 'green' screens, red filters can be used). It is also recommended to change the safe light filters every two years
Ventilation	Adequate filtered and humidified air into the room, and sufficient exhaust to remove fumes

TABLE 5. RECOMMENDED MINIMUM SPECIFICATIONS FOR AN SFM SYSTEM [5, 6, 28, 30–32] (cont.)

Air filter	High efficiency particulate air filters are recommended
Film processor	— Dedicated to mammography or shared system with radiography, ideally optimized for mammography use — Automatic film processor is strongly recommended over manual processing method if budget allows — Suitable for the volume of film processing in the facility — Compatible with water supply in the facility. Water supply ought to be constant pressure, cool enough to properly moderate the temperature in the processor, and free of algae and debris to allow proper washing
Lightproof storage	Bin for unexposed films needs to be placed under the loading bench
	Film viewing and display room
Illuminator	At least 3000 cd/m^2 luminance on a surface that provides diffused light of uniform brightness sufficient to illuminate areas of interest
Environment	Subdued lighting is preferred in the viewing room. It is also important to have a variable brightness high output light source (with appropriate mAs) to view areas of high optical density

3.5.2. Infrastructure and room

An additional and essential room in an SFM facility is the darkroom for film processing. The darkroom ought to be located as close as possible to the imaging room. If a manual film processing method is used, there needs to be a film handling area (dry area) and a processing area (wet area) to minimize the possibility of solution contamination on the film. The darkroom needs to be lightproof and a baffle entrance is recommended as it is more lightproof than a door and permits better ventilation. The darkroom does not have to be black or a dark colour. A suggestion is to paint the walls of the darkroom light green for use with a green safelight or beige for use with a red or yellow safelight. Figure 22 shows the typical layout of a darkroom. If an automatic processor (Fig. 23) is used, a much smaller room can be used.

The darkroom and all the equipment or accessories need to be kept clean all the time as dust can cause artefacts on the film. Chemical spills can also stain the film and screens, hence the solutions need to be covered properly when not in use. There ought to also be adequate storage place (Fig. 24) in the darkroom for unprocessed mammographic films, with appropriate temperature, humidity, and radiation protection measures. It is important to keep the films in a cool and dry room with constant temperature between 10–24°C and 40–60% relative humidity. Humidity below 30% and/or high temperature can lead to cracking of the emulsion causing artefacts on images.

3.5.3. Quality

Additional needs for SFM [5] include:

— Quality control of the film processing, darkroom and the image viewing conditions (by a medical radiation technologist under the supervision of a CQMP). This includes film sensitometry and densitometry performed on every operational day of film processing.
— Development of a programme for detailed reject analysis. This is a significant element for the timely identification of any issue that could affect the diagnostic quality of the images.

3.5.4. Maintenance

Film processors need regular maintenance, including cleaning of rollers and tanks. If an adequate number of films are not processed, the system either needs to be run in a 'batch' mode with the addition of starter chemicals or needs to be shut down on non-operational days. Extended shutdowns result in the need to discard chemicals, clean rollers and replenish the system with fresh chemicals.

Cassettes need to be loaded with film in a dust-free environment, otherwise tiny dust particles will appear as white specks in the resultant images. Regular cleaning of the screens is important. Under very dry conditions there is the risk of electrostatic discharge, which can cause artefacts on film images. Therefore, humidity ought to be controlled.

As part of the imaging system, not only the films but also the cassettes are considered consumable, and they need to be replaced when their performance deteriorates below set limits. This is a cost that needs to be foreseen in the planning of new practices and it will depend on the workload of the department. During their lifespan, it is important that cassettes and screens are kept in good working condition, and a member of the staff (usually the medical radiation technologist) needs to be assigned with the responsibility of their regular maintenance, such

FIG. 23. Sample layout of a room for an automatic film processor. (Image courtesy of Chan Lai Kuan, Malaysia.)

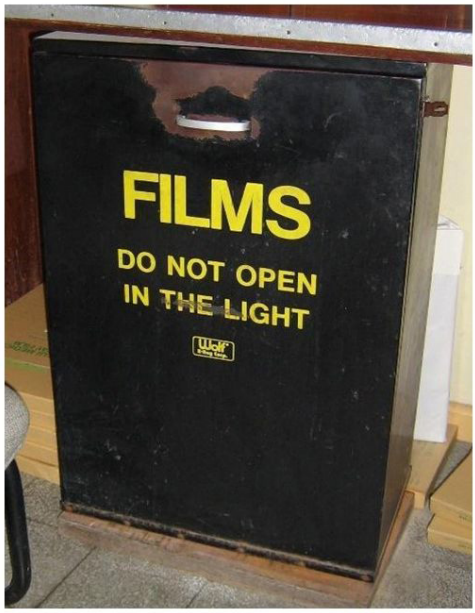

FIG. 24. Example of storage for unexposed X ray films. (Image courtesy of Chan Lai Kuan, Malaysia.)

as cleaning with dedicated products, strictly following the instructions provided by the manufacturer of these components. Discussion on the training of service personnel is found in Appendix VI.

Maintenance ought to be carried out by personnel qualified and trained by the manufacturer. Maintenance logbooks need to be kept up to date. The service provider ought to carry active insurance.

3.5.5. Staff training

The skills needed by the radiologist, medical radiation technologist and CQMP for SFM are listed in Table 6.

3.6. COSTING AND IMPLEMENTATION

The equipment and capital costs to implement digital mammography may be higher at the initial set-up than for other modalities; however, the use of digital technology avoids the need for a range of equipment required for handling, processing, displaying and storing film. For instance, X ray films and processing

TABLE 6. ADDITIONAL SFM SKILLS REQUIRED FOR A RADIOLOGIST, MEDICAL RADIATION TECHNOLOGIST AND CQMP

Personnel	Additional skills
Radiologist	— Basic principles of SFM — Basic understanding of the modality and technique — Image interpretation for SFM — Judgement of clinical image quality and possible artefacts — In-depth teaching at the station on optimal use of the modality — How to overview quality (i.e. images acquired by medical radiation technologists and QC tests)
Medical radiation technologist	— Principles of SFM — Principles of film processing — Modality and technical specifications — Positioning and compression for breast imaging — In-depth teaching on-site on optimal modality use, including AEC function — Film processing technique and basic maintenance — Quality assurance/quality control procedures [5], including: • Daily and weekly QC tests that include darkroom cleanliness, processor QC, phantom images, screen cleanliness, viewing conditions, etc. [11] • Reject analysis • Sensitometry and densitometry of film processing — Identification of artefacts from both QC and patient images
CQMP	— Physical principles of SFM — Advanced knowledge of technical specifications of SFM — Quality assurance protocols for SFM [5] — In-depth knowledge of screen-film image quality and dose optimization

chemicals are not required, therefore reducing consumables cost [33]. There is also no need to store every physical X ray film for an extended period, eliminating a dedicated storage room and additional administrative staff. With DDM, images can be stored digitally in a local hard-disk or a secured cloud system, potentially saving time and improving throughput as well.

All radiological equipment has a limited lifespan; therefore, good management is required to enable efficient operation with minimum disruption in service. Good management would ensure a lower total cost of ownership (TCO), sustained and improved technology infrastructure, and formalized planning and associated budgeting [8].

There are some additional challenges in managing DDM systems [8] due to the following:

— The introduction of software as well as hardware (important also in a CRM);
— Short lifespan for both hardware and software products due to technological obsolescence.

The following paragraphs discuss the costing and implementation strategies of digital mammography in comparison to SFM.

3.6.1. Total cost of ownership

In planning and budgeting to implement mammography, it is necessary to consider the TCO of the equipment, which includes its entire lifespan and the associated supplies [34]. Calculation of TCO usually includes:

— Procurement of the mammography system and the associated equipment;
— Procurement of necessary consumables;
— Maintenance over the lifespan of the equipment;
— Disposal of equipment and consumables.

The typical life cycle of a mammography system is demonstrated in Fig. 25.

The lifespan expectation of mammography equipment is approximately eight (for high utilization) to ten years (for low use) without reduced reliability or image quality [35]. However, digital imaging devices, and especially computer parts, usually need to be updated within three to four years [8]. Therefore, the overall life cycle planning of a mammography system ought to also consider the expected lifespan of all the accessories and their depreciation (if applicable).

The lifespan cost of mammography equipment and its accessories are affected by the local environmental conditions. Hot and humid environments with low quality power supply may lead to substantially higher lifespan costs. Lifespan estimations for different mammography systems [8] are the following:

— X ray system: ten years with normal maintenance and spare parts available,
— CRM system (imaging plate and reader): five years (with good maintenance); eight to ten years (with some updates);
— DDM detectors: six to ten years;
— Computers: five to six years.

Table 7 shows the hypothetical TCO calculation for various mammography systems. For every system, the X ray equipment and

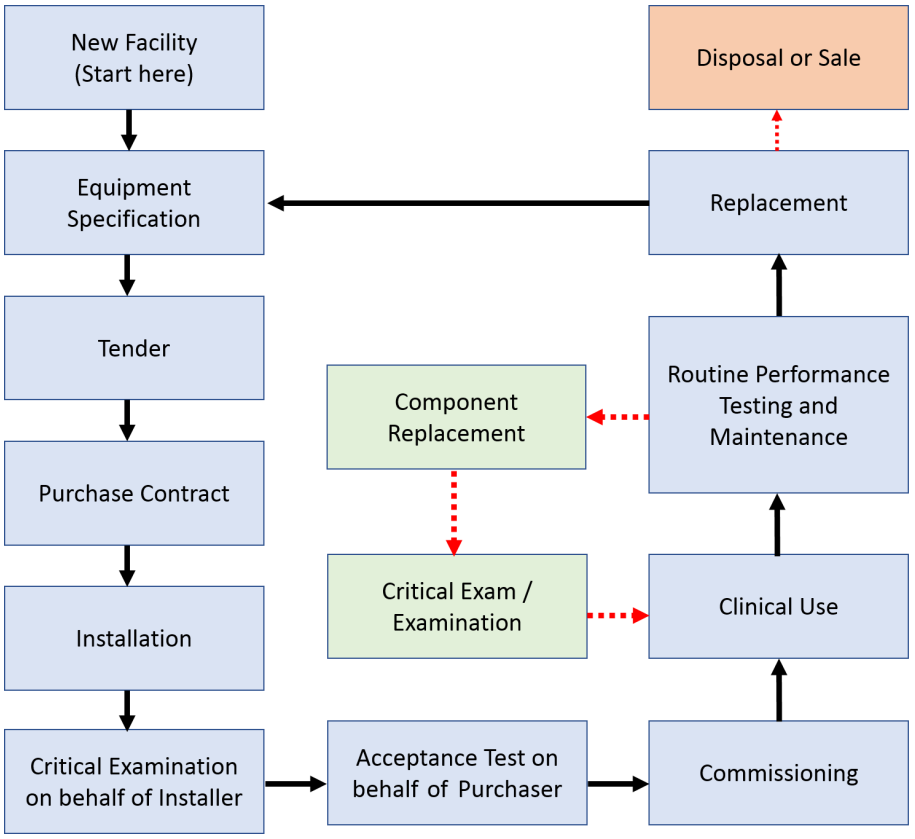

FIG. 25. Sample life cycle of an imaging system. (Image adapted from Ref. [8].)

constituent parts, installation, consumables and maintenance costs (for one to ten years) are included in the budget. Note that the figures displayed in the table are based on sample costing provided by multiple vendors and cover a wide range of products from entry level to advanced systems. The costing is indicative and included for calculation reference only.

TABLE 7. SAMPLE TCO CALCULATION IN EURO FOR VARIOUS MAMMOGRAPHY SOLUTIONS (2018–2021 DATA)

Technological solution	Component	Original price	Installation and consumables, year 1	Maintenance and consumables, years 2–10	Total cost, 10 years
SFM with hard copy reading	X ray system	20 000–60 000	10 000	45 000	75 000–115 000
	Film processor	3 000	1 000	9 000	13 000
	Screen-film cassettes	3 000	1 500	13 500	18 000
	Films/year (1 000 patients/year)	—[a]	3 000	27 000	30 000
	Chemical products/year	—	1 000	9 000	10 000
	SUM	26 000–66 000	16 500	103 500	146 000–186 000
CRM with hard copy reading	X ray system	20 000–60 000	10 000	45 000	75 000–115 000
	CR reader and console	10 000–40 000	2 500	9 000	21 500–51 500
	CR plates	3 000–4 000	—	10 000	13 000–14 000
	Hard copy printer	5 000–12 000	500	4 500	10 000–17 000
	Films/year (1 000 patients/year)	—	3 000	27 000	30 000
	SUM	38 000–116 000	16 000	95 500	149 500–227 500

TABLE 7. SAMPLE TCO CALCULATION IN EURO FOR VARIOUS MAMMOGRAPHY SOLUTIONS (2018–2021 DATA) (cont.)

Technological solution	Component	Original price	Installation and consumables, year 1	Maintenance and consumables, years 2–10	Total cost, 10 years
CRMwithsoft copy reading	X ray system	20 000–60 000	10 000	45 000	75 000–115 000
	CR reader and console	10 000–40 000	2 500	9 000	21 500–51 500
	CR plates	3 000–4 000	—	10 000	13 000–14 000
	Monitors/ PACS (entry level)	50 000–60 000	6 000	45 000	101 000–111 000
	SUM	83 000–164 000	18 500	109 000	210 500–291 500
Retrofitted DDM withhardcopy reading	X ray system	20 000–60 000	10 000	45 000	75 000–115 000
	DR detectors[b]	40 000–50 000	2 500	9 000	51 500–61 500
	Hard copy printer	5 000–12 000	500	4 500	10 000–17 000
	Films/year (1 000 patients/year)	—	3 000	27 000	30 000
	SUM	65 000–122 000	16 000	85 500	166 500–223 500

TABLE 7. SAMPLE TCO CALCULATION IN EURO FOR VARIOUS MAMMOGRAPHY SOLUTIONS (2018–2021 DATA) (cont.)

Technological solution	Component	Original price	Installation and consumables, year 1	Maintenance and consumables, years 2–10	Total cost, 10 years
Retrofitted DDM with soft copy reading	X ray system	20 000–60 000	10 000	45 000	75 000–115 000
	DR detectors	40 000–50 000	2 500	9 000	51 500–61 500
	Monitors/ PACS (entry level)	50 000–60 000	6 000	45 000	101 000–111 000
	SUM	110 000–170 000	18 500	99 000	227 500–287 500
DDM with soft copy reading	X ray system & workstation	125 000–260 000	10 000	90 000	225 000–360 000
	Monitors/ PACS (entry level)	50 000–60 000	6 000	45 000	101 000–111 000
	SUM	175 000–320 000	16 000	135 000	326 000–471 000

a — not applicable.
b — DR = digital radiography.

3.6.2. Cost of storage

One of the major limitations of SFM is the storage space needed for images. The storage room is usually shared with other radiological and medical records in the same hospital or medical centre. According to the Health Insurance Portability and Accountability Act 1996 that is applied in the United States of America (USA), diagnostic images of every adult patient need to be retained for at least five years [36]. Similar act/policy requirements are also applied in other countries, according to their local rules. Proper storage and handling of both processed and unprocessed films is imperative for stability of the radiographic

image. In addition, a security system (such as closed-circuit television, secured access, etc.) ought to also be considered during budgeting.

With digital mammography technology, the need for a physical storage room may be eliminated. The digital images can be saved and easily accessed without image degradation later on. Short term storage (a few days or weeks, if the workload is not heavy) may be achieved by storage within the local hard drive in the modality. Local sharing and teleradiology (i.e. radiology information system and PACS) may be achievable by point to point transmission to the intended users without the need for local storage [8]. Additionally, a separate storage device attached directly to the modality or via a local area network is possible. If there is sufficient Internet connectivity and budget, cloud storage can be considered. Alternatively, images can be burned onto CD or DVD for long term storage, although shelf storage and management may create access and reliability issues. The cost associated with the digital archiving system (including primary and backup storage, IT experts, administrative staff, maintenance, etc.) ought to also be considered during budget planning.

3.6.3. Workload

In DDM, cassettes and X ray films are eliminated, so patient throughput can be markedly improved compared to an SFM or CRM system. In addition, fewer DDM systems may be required because time savings for the medical radiation technologist lead to increased patient throughput. Therefore, DDM is a preferred choice in scenarios with a high workload [2, 37].

DDM could potentially reduce the need for repeat imaging, thereby generating cost savings. The ability to process and magnify images after acquisition may reduce the need to recall patients for assessment. The combination of DBT and full field mammography in DDM has shown improvement in diagnostic accuracy and a reduction in recall rates [38].

Another advantage of digital mammography is the possibility of reducing the need for radiologists to travel between centres for film reading. Images could also potentially be transmitted between centres for expert opinions and used in external quality assessment [33].

3.6.4. Contingencies

All complex projects can experience problems in implementation, unexpected delays and unforeseen problems that raise the cost of installation. Therefore, the budget always needs to factor in approximately 15% of the total cost to support such contingencies [8].

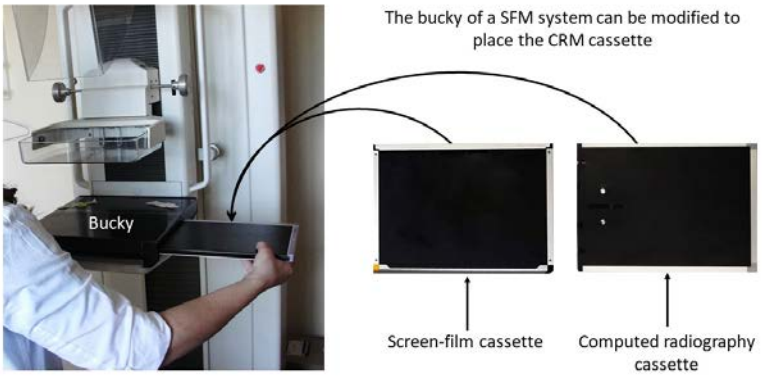

FIG. 26. A bucky from an SFM system can be modified to house the CR cassette without replacing the entire mammography set-up. (Photo courtesy of Konstantopoulio General Hospital, Greece.)

4. TRANSITION FROM SFM TO CRM AND DDM

4.1. GENERAL CONSIDERATIONS

There are several important steps to be carried out when a facility undergoes a transition from SFM to CRM or DDM. In many cases there is a desire to retain the same mammography machine that was used with film (Fig. 26). A new set of cassettes can be purchased to accommodate CR plates together with a readout device, monitor and printer. However, even before procuring these new components, the mammography system needs to be carefully examined to ensure that it is in good operating condition and that its AEC will work properly with the CR plates. A CQMP or, if that is not possible, an appropriately trained service engineer can conduct this evaluation. If the system is not adequate for use with CR plates, it may be necessary to reconsider the decision to convert or to consider purchasing a new mammography unit. If the existing mammography unit is operating properly, it is essential to recalibrate the AEC to ensure it responds appropriately with the new plates and cassettes, which will differ from the SFM system in X ray attenuation, structure of detectors, or image quality indicators. This ought to be done for the range of operations of the mammography system, that is, for the target/filter combinations that will be used and for the range of breast thicknesses and compositions to be imaged. This is an important task of the CQMP, in cooperation with the service engineer(s) for both the plate reader and the mammography unit.

One of the advantages of converting to a digital modality is the ability to transport information electronically from place to place and to maintain records of data such as image acquisition parameters. With CR plates (unlike DDM systems) it is still necessary to physically scan the CR plates in the reader. From that point onward, it ought to be possible for the image and all associated information to be transferred electronically to a PACS or other archiving system. Note that appropriate software licences to do this may be needed. Collecting and moving patient images by having to transfer them onto a portable disk or USB stick is time consuming and inefficient and ought to be avoided if possible. It is possible to incorporate an interface that automatically makes the image acquisition parameters from each exposure available in the DICOM header of the archived image without the need to enter such information manually. Although not absolutely necessary, this is a desirable labour saving feature that contributes to the consistency and quality of imaging.

Unless the digital mammography images will be printed, the film storage will no longer be required except for the storage of historical (i.e. SFM) films. This offers the opportunity to free space for other purposes. On the other hand, it is suggested to digitally archive the digital mammography images and build expertise in digital image management, data security, backup and other IT functions. It is essential to budget for access to this expertise, which in some jurisdictions can be quite expensive.

One of the main values of digital mammography is the ability for the radiologist to manipulate image display characteristics interactively during interpretation of an examination. Mammography workstations have been developed specifically for this purpose. Due to cost or some other compelling reason (e.g. viewers not available for use by surgeon or oncologist), it may be decided to print the mammograms, in which case these interactive features are lost. At the same time there are costs associated with film purchase, processing and the need to have film viewing equipment available. A report entitled “Determining the most clinically and cost-effective way of implementing digital mammography services for breast screening in NHS Scotland” by Brown et al. [37] analyses the transition from SFM to digital mammography services. The report estimated that, assuming a 30% annual increase in throughput for breast screening, it would cost twice as much to replace an SFM unit with a DDM unit than to implement CRM.

Another promising feature of digital mammography is its ability to be used with computer aided diagnosis or artificial intelligence tools. There are currently multiple commercially available artificial intelligence software options for digital mammography and DBT [39], and many more are still under research and development [40]. According to a recent systematic review [40], the use of artificial intelligence in mammography has shown capabilities in

reducing workload, improving diagnostic outcome (with up to 69% reduction in false positives and an 84–94% increment in sensitivity), and independently marking and classifying suspicious findings with abilities comparable with radiologists. It is also possible to better predict breast cancer risk using advanced artificial intelligence techniques such as deep learning convolutional neural networks [41] and hybrid deep learning models that incorporate both the patient's history and radiological images [42]. Sechopoulos et al. [43] have extensively described the basic concepts and developments of artificial intelligence in digital mammography, the pitfalls of conventional methods and future prospects of this encouraging technology. In a white paper published by the European Society of Radiology in 2019 [44], artificial intelligence is foreseen to impact on radiomics, imaging biobanks, clinical decision support systems, structured reporting and workflow.

4.2. RADIATION DOSE CONSIDERATIONS

In mammography, the required dose depends on the X ray energy employed, thickness and composition of the breast as well as the efficiency and sensitivity of the X ray detector. In an SFM system, the absorption efficiency of the phosphor is limited because the screen is thin in order to provide adequate spatial resolution. In addition, relatively low X ray energies are used in mammography and therefore impart higher absorbed dose in the breast. Also, the primary goal in SFM is to achieve a desirable optical density in the linear part of the characteristic curve of the film, which exhibits low dynamic range (particularly important in mammography films). If too few X rays are used, the image will appear brighter than necessary (underexposed) and of poor contrast. If too many X rays are used, the image will appear darker than necessary (overexposed) and again of poor contrast (Fig. 27). Thus, the processed film serves as a sort of crude indicator to determine if the radiation level is appropriate.

With digital imaging, the brightness and contrast of the image are determined in part by adjusting display parameters and are thereby decoupled from the amount of radiation used to form the image. The main reason for this is that the digital detector has much wider dynamic range compared with film, and that allows the same contrast to be created with a wider dose range. Therefore, under- or overexposures can occur without the user being aware of this unless other factors (e.g. mAs used per image or measurements of radiation exposure) are monitored. In the case where too little radiation was used, well trained radiologists and medical radiation technologists might be able to detect regions that are too noisy (granular) but that lack technical information, whereas excessively high doses cannot readily be determined from the image quality.

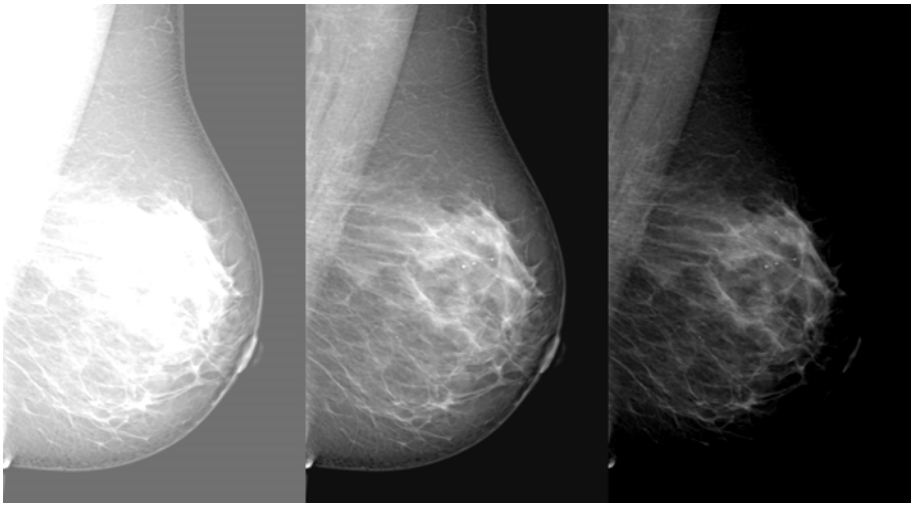

FIG. 27. Examples of underexposure, normal exposure and overexposure (left to right). (Images adapted from [28].)

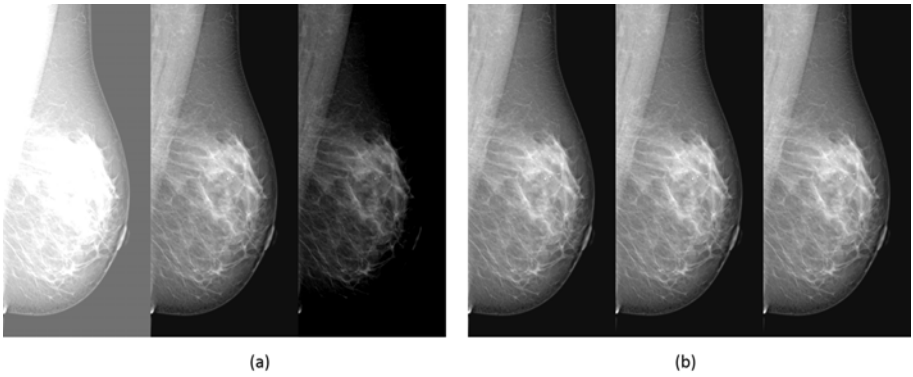

FIG. 28. Comparison of (a) screen-film and (b) digital breast images at underexposure, normal exposure, and overexposure (left to right). (Images adapted from [28].)

Figure 28 demonstrates the differences in appearance between conventional SFM and digital mammography image quality (contrast) in terms of X ray exposure.

In addition, it has been observed that, owing to technical inefficiencies, the dose required to produce a satisfactory CRM image is higher than that required with DDM and may be higher than that required with SFM [26, 27]. If doses for CRM are set to be the same or lower than SFM, then image quality with CRM may be poorer than that previously achieved with SFM. Optimization of dose and

image quality in SFM, CRM and DDM is important and needs to be coordinated and regularly reviewed by the CQMP in collaboration with the medical radiation technologist and the radiologist.

4.3. IMPACT OF TRANSITION

The first publication on a large scale comparison of SFM to the then newly introduced DR system (either CRM or DDM) in a mammography screening setting was from the Digital Mammographic Imaging Screening Trial (DMIST) group in the USA in 2008 [45]. With 33 centres participating and nearly 50 000 women enrolled, participants in DMIST received examinations with (1) DDM or CRM systems and (2) SFM, with independent blind readings of the two examinations. It was found that DDM performed significantly better than SFM for pre- and peri-menopausal women younger than 50 years and with dense breasts, whereas SFM tended to perform better for women aged 65 years or older with fatty breasts. More screening programmes have since reported, and the conclusion remained largely valid: cancer detection rates with a DDM system are very similar to those that can be obtained with a high quality SFM screening programme. However, the outcomes of a breast screening programme depend on many human and technical factors. A simple conversion from SFM to DDM systems without optimization does not guarantee that overall screening results will improve.

Performance of breast cancer screening can be measured in many ways, from cancer detection rate up to more sophisticated measures such as the type of cancers found, the cancer characteristics and the effect on treatment and follow-up exams. A comparative study between SFM and DDM in Norway showed that screening with DDM is associated with less harm than with an SFM system because of lower recall and biopsy rates and higher positive predictive values after biopsy [46]. In Ireland, recall rates and cancer detection rates increased for at least two years after the transition to digital screening mammography, while the positive predictive value declined after this transition period, primarily in patients with microcalcifications [47].

These performance measures allow evaluation of the ultimate impact of DDM equipment for screening and its effect on society, which is important to justifying the investment in the screening programme in general or into an upgrade of equipment or techniques.

To evaluate the effects of their transition to a DDM system, the Dutch and Italian screening programmes have revisited their data prior, during and up to several years after digitization. Their results show that there is a learning curve; the impact of DDM ought not to be judged only by the first years after

implementation. The Dutch screening programme [48, 49] initially reported an increase in the proportion of occult interval cancers during the transition from SFM to DDM systems. However, this increment was temporary and was no longer detectable after initial adjustment. Tumour characteristics and the required type of surgery of interval cancers detected prior to, during and after the transition from SFM to DDM screening mammography were comparable, except that there was a lower proportion of invasive ductal cancers after the transition. In Italy [50], the introduction of DDM had a negative effect on specificity at first, thereby increasing recall rate. This effect existed only over the first 12 months after the introduction of DDM. It needs to be mentioned that, despite this transient effect, baseline recall rates were quite low because of the practice of double reading by experienced radiologists. In line with other reports, they did not observe any difference in the detection rate.

Some publications showed that DDM systems are better than SFM systems at detecting microcalcifications. A study in the United Kingdom [51] showed that cancer detection rates were significantly higher for DDM than for SFM in women less than 50 years old (in line with the DMIST trial) and when cancers had clustered microcalcifications. In Ireland [52, 53], there were significantly fewer interval cancers in association with microcalcification following screening with DDM systems than with SFM systems. This was the logical consequence from the detection of more clustered calcifications in the screening with DDM. While these calcifications are known as suspicious breast lesions, it is not certain, however, whether they will develop into a breast cancer. Neal et al. [54] noted that the mammographic manifestations of atypical ductal hyperplasia and lobular neoplasia are their calcifications, appearing in small clusters or groups of coarse, indistinct or pleomorphic calcifications. Biopsy is often required to exclude ductal carcinoma in situ or invasive cancer. These findings led to several discussions on overdiagnosis or over treatment. It is important to realize that a switch to DDM or to an improved use of mammography will in general lead to the detection of smaller lesions that require work-up and possibly treatments for which services and infrastructure need to be available.

There are also differences in quality between different digital technologies (see Appendix II). In the French screening programme [55], with a large proportion of CRM systems, DDM was found to have a significantly higher detection rate than SFM for dense breasts and for tumours of high grade. The data also indicate that CRM systems detected fewer tumours than SFM and DDM systems in most instances.

In 2014, the French National Cancer Institute reported that, in the French screening programme, breast cancer detection rates were consistently lower with CRM than with DDM systems by 0.7 per 1000 examinations, a reduction of about 10% [55]. At the same time, the rate of technically inadequate examinations

was higher with CRM by approximately 0.8 per 1000 examinations, a relative increase of 44%. In the Ontario (Canada) breast screening programme [38], a 31% lower sensitivity of CRM versus SFM was shown.

In Flanders (Belgium) [26], no significant change in detection fraction had been observed between CRM and DDM. This may be because CRM was operated at a 60% higher overall MGD. Further analysis by Timmermans et al. [56] showed a strong increase in the interval cancer rate with breast density class, independent of the imaging modality that had been used, except for the Breast Imaging Reporting and Data System density '4' or 'd' category, where a decrease of the cancer detection rate was noted for SFM and CRM systems but not for DDM systems. DDM is clearly superior to SFM for dense breasts with respect to cancer detection rate, an observation in line with the first results of the DMIST trial [45]. These observations suggested the value of more personalized screening, where women with denser breasts are offered additional imaging, especially if CRM or SFM is used.

A careful selection of equipment and its subsequent implementation is required in order to achieve the positive impact of the applied technology on the screening results. The literature also shows that an SFM system can perform similarly to DDM if performed carefully. Even digital imaging with printed film can be acceptable, although it is not an efficient approach [57]. Proper planning, implementation, continuous training and optimization ought to be in place to ensure smooth transition and avoid any risk to the patients.

4.4. FIXED INSTALLATIONS VERSUS MOBILE SERVICES

Generally, mammography is most effectively carried out at a fixed location in a hospital, clinic or health centre. This allows the imaging procedures to be carried out by staff supporting the clinical activities and having access to medical emergency facilities, maintenance, cleaning services, etc. In addition, the supply of electricity is more likely to remain stable as is the environmental temperature and humidity. It is usually easier to expand capacity at a fixed location [13].

On the other hand, there are reasons for delivering mammography and particularly screening mammography from a mobile vehicle such as a bus, van or possibly a boat or aircraft. Mobile mammography makes sense particularly in regions where populations are sparse or access to medical personnel is very limited [58]. The advantage of this approach is that it is more efficient in concentrating skilled individuals, high quality equipment and a rigorous QAP in one centre, making them available to the public over a wide area.

A single mammography system housed on a bus (Fig. 29) can visit many communities on a schedule, which allows the public to receive examinations

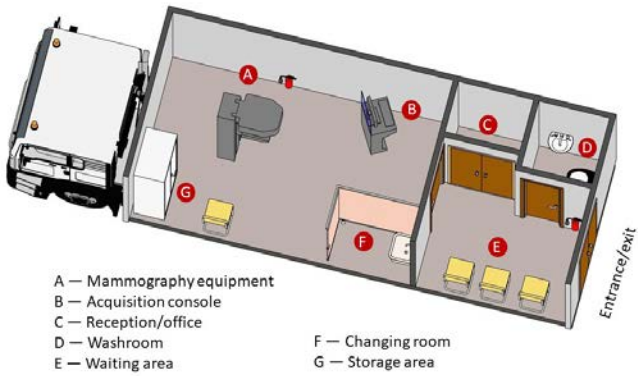

FIG. 29. Sample layout of a mobile mammography unit.

without having to travel long distances from their homes. Those communities may not be large enough to sustain a fixed facility each. If equipment is underused, staff are also unlikely to perform enough examinations to maintain their skills.

Mobile mammography services ought to be operated by dedicated, highly skilled staff, and equipment needs to be properly maintained. If it is not possible for a radiologist to be present, certain breast intervention procedures will not be possible, but most diagnostic examinations can be carried out, as well as breast screening. Images can be transmitted from the mobile unit to the radiologist either via USB/flash drive, hard copy or Internet. Other logistics are needed when interventions such as a biopsy are required.

The other special considerations for mobile mammography include the effects of transportation. Mobile systems may need to travel along poor quality roads, making it potentially hazardous to transport the wet chemical solutions needed for SFM systems. In such cases, a digital solution may be preferred. DDM is more suitable than CRM as the need for a mechanically sensitive reading device is eliminated.

In any case, efforts ought to be made in vehicle design to provide as much shock damping as possible to protect equipment. Special approaches need to be taken to purchase equipment that is ‘ruggedized’ and in mounting the equipment so that it is least likely to be damaged in transit.

It is important to incorporate provisions for the climatic conditions to which mobile mammography facilities may be exposed, especially with consideration of the temperature limits of the detector. Some detectors are destroyed if the temperature rises above 40°C or falls below –10°C while they are not in use. Backup air-conditioning systems or other mitigating mechanisms may be needed

in harsh climates. The supply of required external connections to electrical power, water and Internet also need to be planned.

Ideally, the mobile facility would have an Internet connection over which patient bookings could be downloaded from the radiology information system in the form of a worklist. This prepopulates the patient demographics and results in easier workflow and reduced chance of data entry errors. Because of the mechanical stresses imposed on equipment that is being moved regularly, the implementation of and attention to a rigorous (and more frequent) QAP is particularly important.

5. CONCLUSIONS

X ray mammography is a proven technique for early detection of breast cancer and is widely used for its diagnosis, localization, biopsy and follow-up, although there are specific roles for other breast cancer imaging modalities.

DDM is generally the optimal technology for mammography imaging. In some cases, however, financial constraints, environmental conditions, lack of qualified individuals and technical support may drive the adoption of other solutions, such as CRM or SFM technology. It may be more appropriate and provide better community service to establish a mobile breast imaging programme. Therefore, careful considerations and thorough planning are needed to ensure a beneficial and optimal implementation of breast cancer imaging. This publication considered different scenarios and approaches to establishing breast cancer imaging or making a transition to achieve improved performance. Tools are provided to facilitate these decisions with emphasis on the resources (human, technological, support and training) required in each case.

The infrastructure of a mammography facility ought to include communication and connection with other departments and specialties such as pathology, oncology, breast surgery, etc. With the implementation of digital imaging (e.g. DDM and CRM), data can be shared within a secured network in a more effective and timely manner. This also facilitates telemammography or telemedicine when remote expertise is required.

Additional benefits of digital imaging include better image quality and dose optimization, facilitating better diagnosis. Multiple studies have shown that DDM and CRM result in a lower recall rate in combination with higher detection rates and decreased positive predictive value of recalls than SFM [47, 59–64]. Multiple image analysis software and artificial intelligence tools can be applied to digital images to aid diagnosis, improve workflow and predict breast cancer

risk, and hence enhance the overall performance of mammography diagnosis, screening and breast cancer management [65]. Though artificial intelligence is likely to integrate into clinical practice in health care, its implementation needs to be carefully considered to evaluate its clinical value as well as issues of training, bias and transferability, data ownership, confidentiality and consent as well as legal, moral and professional obligations [66, 67].

Appendix I

BREAST CANCER

Breast cancer is the most frequently diagnosed cancer and the most frequent cause of cancer death on a worldwide basis [1]. More than two million cases of breast cancer are diagnosed every year [4]. Breast cancer constitutes over 11.7% of the new cancer cases in women, with the next most frequent cause, lung cancer, representing 11.4%. Breast cancer accounts for 6.9% of the deaths [4]. The epidemiology studies show an alarming trend of steadily increasing incidence worldwide, due not only to increased detection and reporting, but actually reflecting a true increase in the incidence of breast cancer (by about 30% to 40% from the 1970s to the 1990s), including detection at more advanced stages.

Breast cancer is the most common cause of death from cancer in women globally, with 685 000 deaths attributed to it in 2020 [68]. The WHO estimates that 8.4 million women will die of breast cancer in this decade if breast cancer care is not improved [69]. While mortality related to breast cancer is decreasing in developed countries, the contrary is projected in LMICs [34, 70]. It is estimated that 45% of 1.35 million new cases of breast cancer occur in LMICs and that 55% of deaths from breast cancer are in LMICs [71, 72]. The higher mortality from breast cancer in LMICs is related to lower awareness of the importance of early detection and lack of facilities for early diagnosis and treatment.

I.1. STAGES OF BREAST CANCER

Stage refers to the level of progression and/or spread of the breast cancer. The prognosis for cancer patients becomes progressively worse with each increasing stage. A full description of the stages includes information about the size of the tumour, the degree of spread, the grade (degree to which the appearance of the cells differs from those of normal breast cells) and the receptor characteristics of the cancer cells. The receptor characteristics of the cancer cells refer to whether or not the cells express increased numbers of certain molecules associated with the aggressiveness of the cancer, most notably oestrogen and progesterone receptors, the so-called HER2 receptor and a molecule called Ki-67.

Stage 0 — It is assumed that virtually all breast cancers originate in transformed cells located within the epithelial (ductal and lobular) structures of the breast. In this initial stage, also referred to as in situ cancer, cells remain within the confines of those structures. Ductal carcinoma in situ, therefore, is

not a lethal disease. These early cancers become dangerous because some of them have the capability of progressing beyond the basement membranes.

Stage I — Cancer cells that have escaped the confines of the ducts are referred to as invasive cancers. In this early stage, cancer cells have not noticeably spread from the primary location to lymph nodes or beyond. There are substages defined according to the size of the tumour in the breast (2 cm or less) and the presence or absence of a few cancer cells in the local lymph nodes.

Stage II — Such cancers are those that have spread (metastasized) further from their initial site. Some cells produced by the cancer have been collected by the lymph nodes in the axilla (underarm). This is a route toward more widespread metastases. Substages are related to the size of the tumour (2–5 cm) and the presence, or absence, of cancer cells in up to three local lymph nodes.

Stage III — This stage has three substages (a, b, c), and its definition is complex, but some features include large tumours (>5 cm) or spread to skin of the breast or chest wall or spread to lymph nodes even above the collar bone.

Stage IV — In this stage, cancer cells have spread to and established residence in other organs and tissues including the brain, liver, lung or bone.

I.2. INCIDENCE

Once a disease mainly associated with wealthier countries, breast cancer incidence is now increasing in Asia and Africa. Because of large populations, among the highest number of breast cancers appearing annually occur in Asia. When expressed as rates per 100 000 population, there is a twentyfold difference between countries with the highest breast cancer incidence (204/100 000 in Belgium) and those with the lowest incidence (15/100 000 in Bangladesh and 10/100 000 in Tanzania) [4]. While the highest incidence rates are still observed in Europe, Australia and New Zealand and North America, the rates are rising quite slowly over time. Conversely, rates are rising most quickly in countries that have low and middle incomes, such as Uganda and China.

I.3. BREAST CANCER MORTALITY

In terms of mortality, patterns are similar, with the number of breast cancer deaths being highest in Asia, although age standardized mortality rates tend to vary less. A much higher proportion of women who are diagnosed with breast cancer die of the disease in countries that have a low human development index. Santucci et al. studied trends over time between 2000 and 2016 in France, Germany, Italy, Japan, United Kingdom and the United States of America and found that breast

cancer mortality fell 1.0% to 2.5% on average per year in every country except in Japan where there was an annual increase of 1.4% [73]. Incidence increased in most of these countries at annual relative rates of between 0.3% and 1.0%. Japan, however, showed the highest rate of increase in incidence over this period of 5.2% per year, although the values of both incidence and mortality themselves are the lowest among these countries. Santucci et al. also observed an increase in survival over the period in all the countries studied although survival rates varied considerably, being lowest in the UK and highest in Japan [73].

When the mortality rates are graphed versus incidence rates (Fig. 30), there is an overall positive correlation between the two among different countries. Examples of countries with high incidence, in which mortality is in the middle of the cluster are Argentina, Lebanon, Singapore and Jordan. It is instructive, however, to consider the outliers. In some countries with medium and high reported incidence rates, mortality is markedly lower than the trend line. Examples of these countries are Australia, Canada, Finland, Republic of Korea, Malta, Norway, Portugal, Spain, Switzerland and the United States of America. This is likely due to a combination of earlier detection, relatively prompt and effective treatment and thorough, efficient reporting through cancer registries. Also seen are countries where reported incidence is relatively low, but mortality is disproportionately high. These include the Central African Republic, Equatorial Guinea, Fiji, Niger and Somalia. One possibility is that the actual incidence is higher than recorded due to incomplete incidence reporting. Another possibility is that, in the absence of screening programmes, breast cancer is detected only when it is symptomatic and access to high quality treatment is very limited. In their study of breast cancer outcomes in India, Mallath et al. identified that the ratio of mortality to incidence is negatively correlated with the human development index [74].

I.4. BREAST CANCER SURVIVAL RATES

In the comprehensive study known as CONCORD-3, Allemani and colleagues analysed the 5-year survival rates of over 6.4 million women from 66 countries who were diagnosed with invasive breast cancer between the years 2000 and 2014 [75]. They found that the current 5-year survival rate for breast cancer stands at 89.5% in Australia and 90.2% in the United States, yet there are considerable international variations, with rates as low as 66.1% in India [75]. The researchers observed that survival rates ranged from 70% to 79% in 12 countries, which included Cuba and Ecuador; Kuwait and Mongolia; and eight European nations (Estonia and Lithuania from Northern Europe; Croatia from Southern Europe; as well as Bulgaria, Poland, Romania [Cluj], Russia and

Slovakia from Eastern Europe) [75]. While there was a general improvement in breast cancer survival rates between 2000 and 2014, significant differences in the rate of progress persist among countries, with many Eastern European countries still experiencing low survival rates. An excellent overview of the international patterns of breast cancer incidence and mortality, and projections of these into the future for countries at different levels of development is provided by the International Agency for Research on Cancer [76]. It is predicted that in the most developed countries, breast cancer incidence will increase by 16% between 2012 and 2025 while deaths will increase by 24%. In countries with the lowest human development indices, it is expected that incidence will increase by 47% and deaths by 57%.

I.5. STAGE AT DETECTION

In jurisdictions where earlier detection or screening programmes do not exist, breast cancer tends to be detected when tumours are larger and at a more advanced stage. In Mexico, a 2017 publication indicates that 49% of breast cancers are diagnosed at Stage III/IV [77]. In a 2002 report from Chennai,

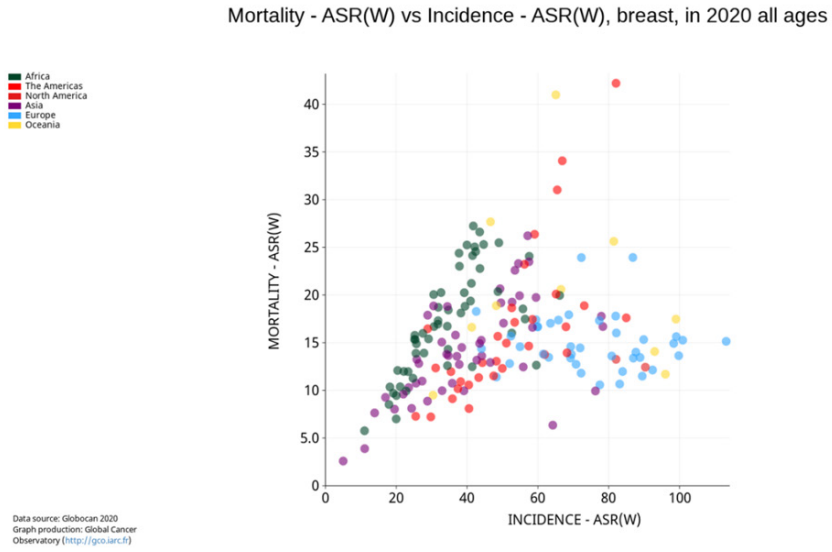

FIG. 30. Mortality due to breast cancer compared to its incidence in various countries [4]. Note: North America contains data from USA and Canada, whereas the Americas include data from both North and South America.

India, only 1.0% of cancers were detected at Stage I, 23% at Stage II and three quarters at Stage III or IV [78]. Jedy-Agba et al. carried out a systematic review of data on diagnosis of breast cancer in sub-Saharan Africa and found that 74.7% (median value) of breast cancers were found at Stage III or IV [79]. There was wide heterogeneity between different regions (30–100%) in the proportion of cancers diagnosed at a later stage, with the percentage being higher in Black women than in women who are not Black, and higher in rural than urban areas. In some of the reports listed, these later stage cancers accounted for over 90% of the cancers diagnosed. Furthermore, in sub-Saharan Africa most of the breast cancers were diagnosed in women aged 35–49. The percentage of late-stage cancers fell gradually between 1980 and 2000, but both the rates and the rate of decline continue to be much higher than in most of Europe and North America. The authors compared these data with the USA, where between 1973 and 2011 the percentage of Stage III/IV cancers fell from 60% to 27% in White women and fell from 60% to 32% in Black women, while rates in Black women in sub-Saharan Africa are still well over 60%.

Kim et al. surveyed regional variations of breast cancer outcomes in Asia and found that the proportion of Stage III/IV cancers among breast cancers diagnosed was highest in the Philippines (42%) and Jordan (35%), intermediate in China (26%) and Israel (Jewish population) (23%) and lowest in Japan (12%), Hong Kong, China (18%) and the Republic of Korea (19%) [80].

In Canada, Davidson et al. demonstrated a marked downward shift in stage at diagnosis associated with participating in an organized screening programme; 9% of cancers were found at Stage III/IV in participants versus 21% in non-participants [81].

I.6. BREAST CANCER SCREENING

Screening is the routine examination of asymptomatic individuals for the purpose of detecting a disease earlier, before it presents symptoms. It has been demonstrated in randomized controlled trials, case-control studies and observational studies of real-world screening programmes that regular high quality screening with X ray mammography can contribute to marked reductions in mortality from breast cancer [82–86].

Through earlier detection, screening can often also make it possible to treat smaller cancers at an earlier stage, allowing less harsh therapies to be used: breast conserving surgery rather than mastectomy, avoidance of axillary dissection and chemotherapy [87–91]. While breast cancer screening can be effective, it is not an efficient process in that typically only between 2 and 10 cancers will be detected per 1000 examinations. In addition, depending on how screening is

practised, between 3% and 15% of women will have at least slightly suspicious findings upon initial examination, prompting the need for further imaging. If results remain positive, definitive diagnosis of cancer is then obtained by biopsy, currently often performed using a core needle method. Typically, between one third and one half of the biopsies performed are positive for a diagnosis of cancer. Screening, therefore, requires considerable resources: a mechanism to invite women to have their regular examinations and to convey results back to them, imaging equipment, a medical radiation technologist to perform the exam by positioning the breast and acquiring the images, a radiologist to interpret the examinations, access to biopsy, pathology to provide the diagnosis, and surgical, medical or radiation therapy as well as maintenance and QC of the imaging equipment.

Before attempting to implement a screening programme, all these factors ought to be considered. Providing these necessary components may be extremely challenging. Anderson et al. argued that earlier detection of symptomatic cancer needs to be in place before embarking on screening and they proposed a sequential action plan for moving in this direction, particularly in LMICs:

> "1) promote the empowerment of women to obtain health care, 2) develop infrastructure for the diagnosis and treatment of breast cancer, 3) begin early detection efforts through breast cancer education and awareness, and 4) when resources permit, expand early detection efforts to include mammographic screening. Public education and awareness can promote earlier diagnosis, and these goals can be achieved in simple and cost-effective ways, such as dissemination of messages through mass media. All women have the right to education about breast cancer, but it must be culturally appropriate and targeted and tailored to the specific population" [78].

Several documents have been developed to provide guidance on the decision regarding implementing screening and on the design of screening programmes [92–95]. While the principles in these documents continue to apply, some of the documents are old, and both technology for breast cancer detection and treatment options continue to advance. It is important to keep this in mind when referring to these resources.

Appendix II

MAMMOGRAPHY TECHNOLOGY

Mammography is the leading technique for breast cancer diagnosis and the only imaging method that, when used for screening, has been demonstrated to contribute to reduced breast cancer mortality. It is the first line diagnostic test for non-palpable breast lesions. Breast cancer screening programmes (discussed in Appendix I) are well established in many countries worldwide, but there are significant variations in the quality of tests and time intervals between examinations. These vary from mammograms performed every year to one examination every three years. Currently, many LMICs have not invested in screening programmes and preventive medicine because of limited financial resources and health care infrastructure. It ought to also be emphasized that the reliability and sustainability of any screening programmes require strict QA of imaging procedures, from technical issues (e.g. positioning of the breast during imaging, choice of image acquisition parameters, image quality and calibration of the X ray equipment) to interpretation of the images (e.g. viewing conditions, review of previous images, double reading), evaluation of early recalls, feedback information, multidisciplinary conferences, diagnostic performance indicators and continuing education.

Mammography requires adequate competence and training of dedicated personnel (discussed in Appendix VI) in order to guarantee high quality diagnostic information (high sensitivity and specificity in detecting cancer, thereby minimizing the chances of missed cancers and reducing unnecessary recalls in the case of undetermined findings). It is desirable that a mammography facility provide a short waiting time for appointments and a friendly and inviting atmosphere. The role of the medical radiation technologist needs to be highlighted at this point, especially in terms of personal communication and interaction with the patient. As the medical radiation technologist is usually the only health professional the patient will meet, it is important to have adequate training, skills and competencies to deal with this sensitive situation.

The diagnostic accuracy (especially sensitivity) of mammography is suboptimal in subjects with so-called ‘dense’ breasts; sensitivity can be as low as 65% in dense breasts, compared to 85–90% in mainly fatty breasts. Doubtful cases can be clarified by other imaging modalities such as ultrasound, MRI and mammoscintigraphy (the latter being used much less commonly).

II.1. BREAST IMAGING WITH MAMMOGRAPHY

Mammography is an X ray examination of the breast. Images are acquired at relatively low X ray energy with the breast placed between an image receptor (recording device) and a compression plate which is used to reduce the thickness of the breast to improve image quality and decrease the dose to the patient.

Although mammography plays an important role in the early detection of breast cancer, it has been demonstrated that when the quality of the mammograms is not sufficiently high, the ability to detect cancers earlier is impaired [96]. In breast cancer screening (Appendix I), reduced accuracy of mammography is associated with worse outcomes of the screening programme.

A high quality mammography image is one that has the following properties:

— The breast is properly positioned;
— There is excellent contrast over as much of the breast as possible;
— There is adequate sharpness (spatial resolution) throughout the breast area;
— There is no excessive noise that can degrade the imaging of the anatomical structures;
— There are no disturbing artefacts that can resemble pathological findings or obscure proper diagnosis;
— The imaging examination delivers as low a radiation dose as low as possible, consistent with the required image quality, keeping in mind that the examination can be performed on healthy women without any symptoms.

Image quality is associated with the performance of the equipment as well as with the manner in which it is used. Equipment performance depends on its design and manufacturer but also on whether it is properly maintained and adjusted over time. Figure 31 shows an example of a mammogram acquired in MLO projection.

II.2. OVERVIEW OF MAMMOGRAPHY X RAY TECHNOLOGIES

II.2.1. Components of a mammography system

Mammography X ray technology has improved remarkably since the turn of the 21st century. When purchasing a new or used mammography machine, one ought to expect the system to have a high frequency power supply to energize the X ray tube, capable of delivering tube voltages up to 49 kV. The tube needs to have a design specifically for mammography that includes a molybdenum, rhodium or tungsten target with two sizes of focal spot to permit both contact

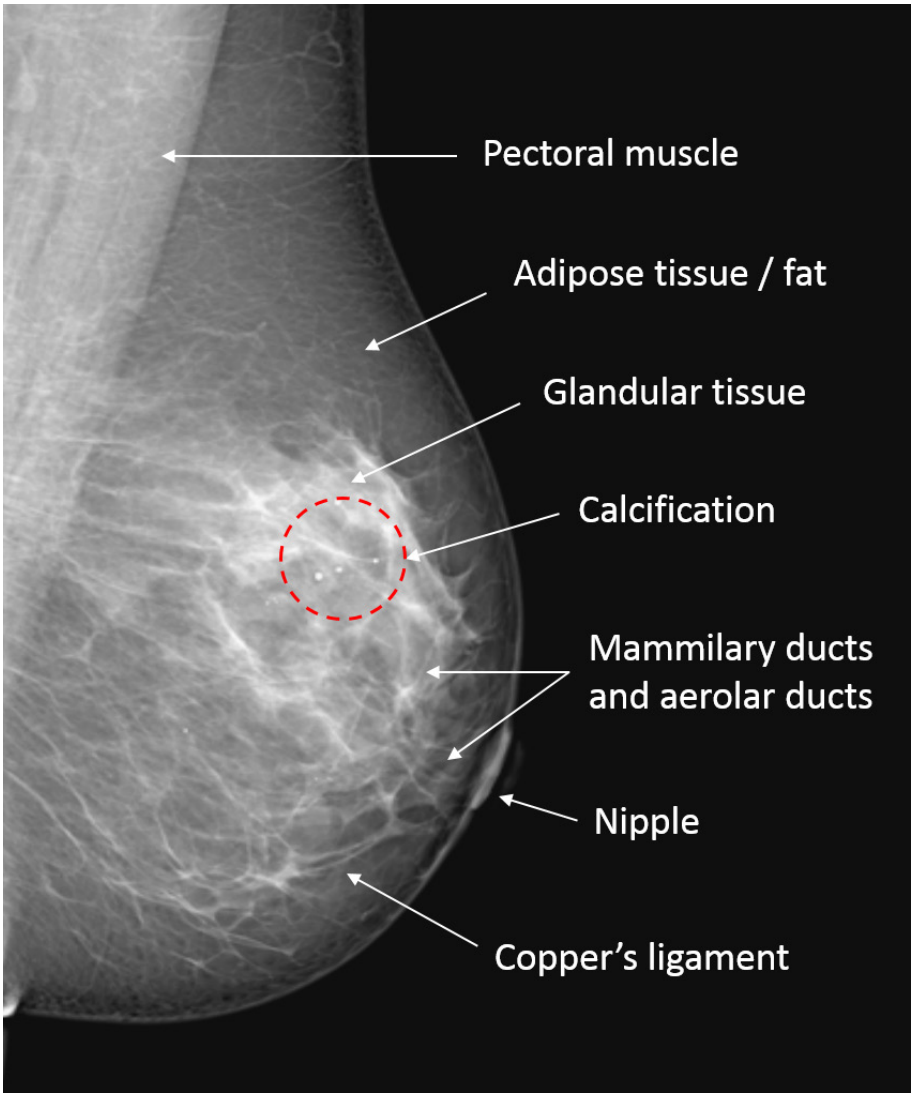

FIG. 31. Example of a mammogram acquired in an MLO projection. Characteristic benign calcifications (in red circle) are seen in this mammogram. (Image adapted from [28].)

and magnification imaging. The X ray field ought to be able to cover the entire breast with a single exposure. Appropriate metallic beam filters matched to the available target materials need to be in place.

The system ought to provide collimation to define the X ray field for exposure and have an integrated optically transparent compression plate

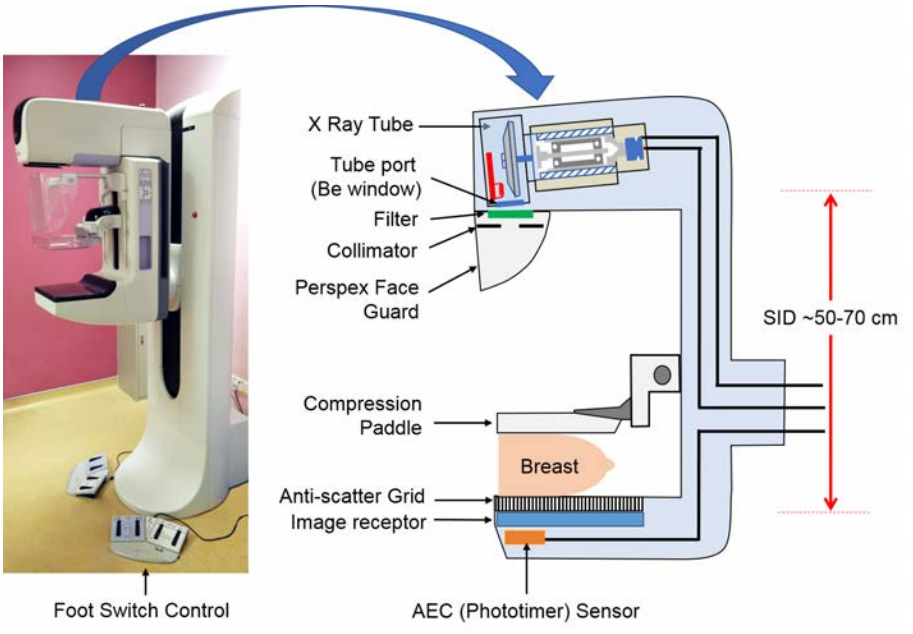

FIG. 32. Main components of a typical mammography X ray equipment.

with a mechanism for controlled compression of breast thickness and a safety mechanism to avoid overpressure. An antiscatter grid, with either a motion mechanism to blur grid lines or a dedicated stationary grid with sufficiently high pitch so that grid lines do not interfere with the image, also need to be integral to the system. An AEC device which senses the amount of radiation transmitted through the breast to reach the image receptor is essential. Other desirable features include readout of breast compression thickness and force or pressure and automatic selection of exposure parameters such as target/filter combination and kilovoltage on the basis of information about the breast gathered from a short low dose pre-exposure and the readout of compression thickness. Figure 32 illustrates the main components of typical mammography X ray equipment.

II.2.2. DDM technology

Digital mammography, introduced commercially in 2000, is able to overcome many of the technical limitations of screen-film mammography. In digital mammography, image acquisition produces a digital image that can then be further processed, displayed and stored independently, allowing for optimization of each step. Acquisition is carried out using low-noise X ray detectors with a

broad dynamic range. The resultant image can be digitally stored and displayed with a contrast that does not depend on detector characteristics but is determined by the specific imaging task requirements. A variety of helpful image processing techniques can be conveniently applied before displaying the image. These techniques may include anything from straightforward contrast improvement to altering the histogram and spatial frequency filtering to enhance image sharpness or minimize noise.

The hurdles in developing a digital mammography system with enhanced performance largely revolve around the X ray detector and the display apparatus. The detector exhibits the following features:

— Efficient absorption of the incoming radiation beam;
— A response that is linear or logarithmic across a broad spectrum of incident radiation intensity;
— Minimal inherent noise and virtually no fixed pattern noise, to ensure that images are X ray quantum noise limited;
— A limiting spatial resolution on the scale of 5 to 10 cycles/mm (50 to 100 μm sampling);
— It can handle a field size of at least 18 × 24 cm and ideally a 24 × 30 cm;
— It has the capability to image immediately adjacent to the chest wall;
— A satisfactory image capture duration and heat handling capacity of the X ray tube (for instance, in detectors that ideally require scanning to image the entire breast).

There are two main approaches in detector development — area detectors and scanning detectors (Fig. 33). Most commercial systems adhere to the initial method where the complete image is captured all at once. In contrast, scanning systems acquire only a fragment of the image at a time, and the entire image is compiled by moving the X ray beam and detector across the breast. Area detectors provide quick image acquisition and can be utilized with traditional X ray machines equipped with a grid to minimize scatter. On the other hand, scanning systems have extended acquisition durations and are mechanically more intricate, but employ relatively uncomplicated detectors and exhibit superior inherent scatter rejection [28].

Various detector technologies are employed in DDM systems.

In so-called ‘indirect’ detectors (Fig. 34), each del (detector element) includes both a light sensitive photodiode (i.e. amorphous silicon (or a-Si)) and a thin film transistor switch. The array is covered with a phosphor layer, typically made of thallium activated CsI (caesium iodide (CsI:Tl)). X rays transmitted by the breast are absorbed by the phosphor and the light produced is converted in the photodiode to charge, which is stored on its capacitance. The array in

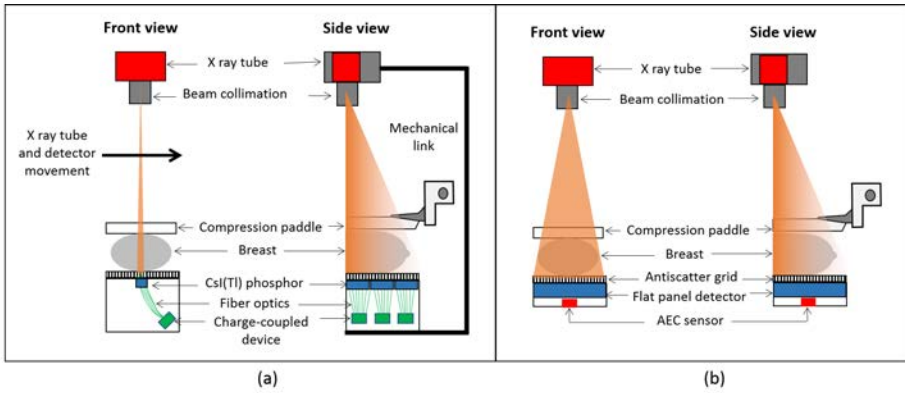

FIG. 33. Comparison of (a) a scanning detectors system and (b) an area detector system of a typical DDM system.

question is coated with a phosphor layer, usually comprising thallium-activated CsI (caesium iodide, CsI:Tl). X rays passing through the breast are absorbed by the phosphor, which then emits light. This light is transformed into electrical charge by the photodiode, and this charge is stored in its capacitance. Following the X ray exposure, signals are sent along each row one by one, triggering the corresponding switches. This process moves the charge down the columns towards readout amplifiers and multiplexers, where it is subsequently digitized to create the image. This reading system enables the extraction of signals from the dels in a very short time. The needle-like crystals of CsI, which behave a bit like fibre optics, direct the light to the photodiodes with less sideways dispersion than granular phosphors would cause. This property allows for a thicker phosphor layer compared to a granular one, enhancing the detector's X ray detection efficiency without significantly sacrificing spatial resolution.

'Direct' detectors employ a similar readout strategy but, instead of a phosphor, employ an X ray absorber composed of amorphous selenium (a-Se), which is a photoconductor. In these detectors:

> "… the energy of the absorbed X rays causes the liberation of electron hole pairs in the selenium. The charged particles are drawn to the opposite faces of the detector by an externally applied electric field. To collect the signal, an array of electrode pads (rather than photodiodes) forms the dels. Unlike the phosphor based detectors, the electric field can be tailored to collect the charge with minimal lateral spread. This allows the use of a relatively thick detector to achieve excellent QDE [efficiency] without significant reduction in resolution at near normal incidence (Fig. 35) [28]."

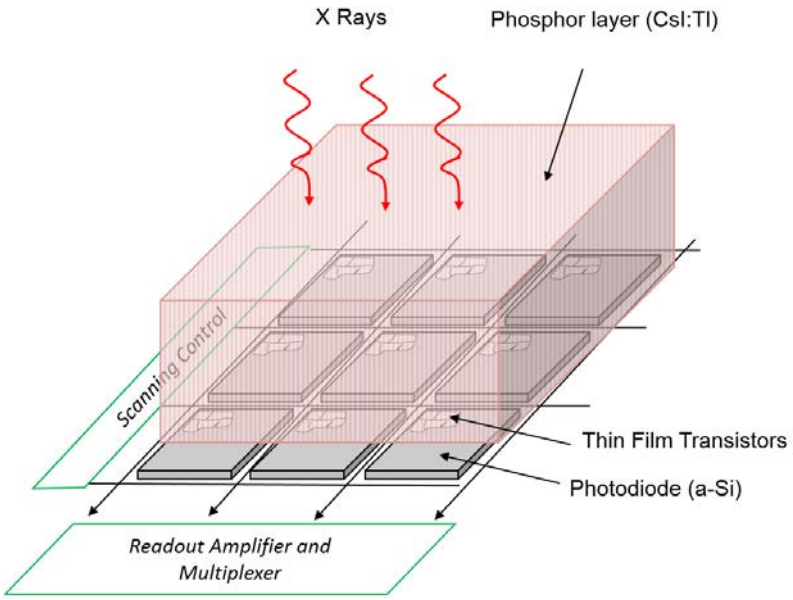

FIG. 34. Basic principles of an indirect conversion flat panel detector. Thallium activated caesium iodide (CsI:Tl) phosphor converts X rays into lights and then they are converted into charges by the amorphous silicon (a-Si) photodiode. The charges are stored in individual thin film transistors and then transferred to readout amplifiers and multiplexers to form a digital image.

II.2.3. CRM technology

A different type of detector technology employed in CRM involves a lightproof cassette containing a plate composed of photostimulable phosphor material. This plate gets excited by electrons when exposed to X rays, and the resulting captured electrons are proportional to the amount of X ray energy absorbed in a specific area of the detector. Following exposure, the plate is placed in a reading device (known as the computed radiography plates reader (Fig. 36)) and is scanned with a red HeNe laser beam [28].

The laser light's energy triggers the release of electrons from the traps, causing them to transition through energy levels within the phosphor crystal, which in turn generates blue light. An effective optical system collects this light, measures it using a photomultiplier tube, and converts it into digital signals. By matching the signal's measurement time to the scanned laser beam's location, the signal can be assigned to a specific image pixel. In CRM, image resolution depends on various factors such as the size of the scanning laser beam, the scatter of the readout laser light in the phosphor and the sample measurement's distance.

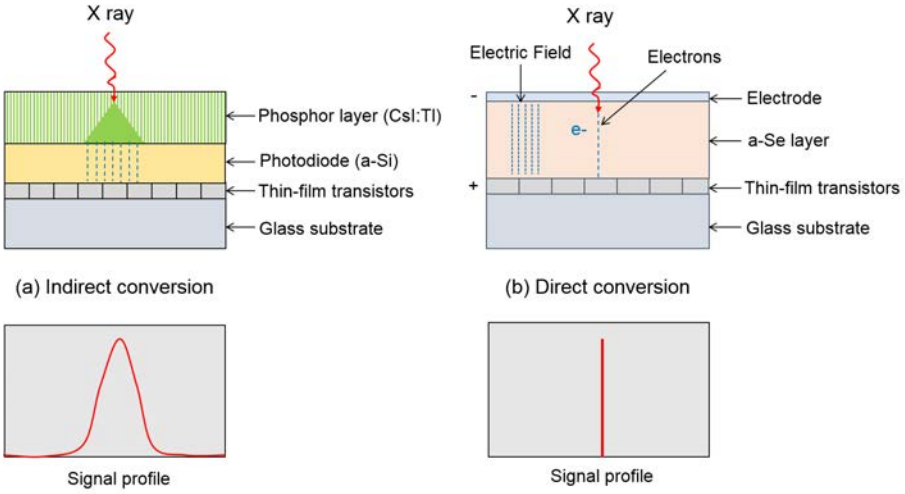

FIG. 35. Comparison of (a) indirect conversion and (b) direct conversion flat panel detector used in DDM systems.

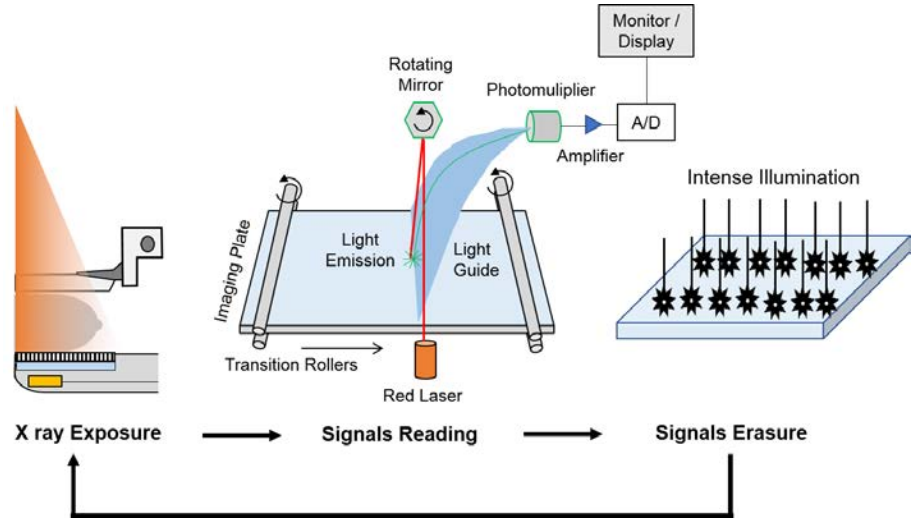

FIG. 36. Basic operations of a CR plates reader.

In mammography photostimulable phosphor systems, several differences exist in comparison to general radiography photostimulable phosphor systems. These mammography systems have been designed to achieve higher spatial resolution, necessitating the use of thinner phosphor materials, and finer sampling

pitch, usually around 50 μm. These factors contribute to reduced signal per pixel, which has been addressed by several innovative techniques. These techniques include using dual-sided readout of the phosphor plates and the use of needle-like phosphors that permit the use of thicker detectors with superior performance. Overall, these adaptations enable the production of high quality images with improved resolution and better sensitivity.

Thus far, the detector systems examined have been acquiring images by aggregating the signal from a number of X ray quanta that get absorbed in the detector, which then undergoes digitization. The noise present in these images is influenced by both the Poisson X ray quantum fluctuations arising from X ray absorption, and additional noise sources related to the production of the electronic signal. These noise sources may emerge from the variation in the amount of light produced by a phosphor after absorbing an X ray with a specific energy level or from the X ray spectrum itself, where different quantities of signal occur as X ray quanta of differing energies interact with the detector material.

Alternatively, one could directly tally the interacting quanta, sidestepping the extra noise sources in the process. Quantum counting detectors, usually designed as multiline devices, commonly utilize a set-up where the X ray beam is collimated into a single or multiple slits. This beam is then systematically moved across the breast to gather the necessary imaging data. The detector's basis could be either a solid-state method, which generates electron hole pairs in a substance such as crystalline silicon, or a pressurized gas method where the signal is constituted by ions formed within the gas. Regardless of the method, the charge signal's collection and suitable amplification result in a pulse for each X ray quantum interaction. These pulses are then simply tallied to form the signal. Another characteristic of these detectors is their collimation of the beam to only expose a section of the breast at a time. This reduces the scatter to primary ratio (SPR) without requiring a grid, thereby enhancing the system's dose efficiency [28].

II.2.4. Comparison among mammography technologies

There are two general forms of mammography technology currently in use: analogue systems like SFM and digital systems. Digital systems are further subdivided into two types: CRM and DDM systems.

In SFM systems, X rays transmitted through the breast are absorbed by a fluorescent screen, producing a pattern of light representing the relative transmission of the X rays through different areas of the breast (Fig. 37). A sheet of photographic film pressed tightly against the screen records that light pattern. The screen and film are contained in a lightproof cassette. After the X ray exposure, the film is transferred to a processor where chemicals are used to

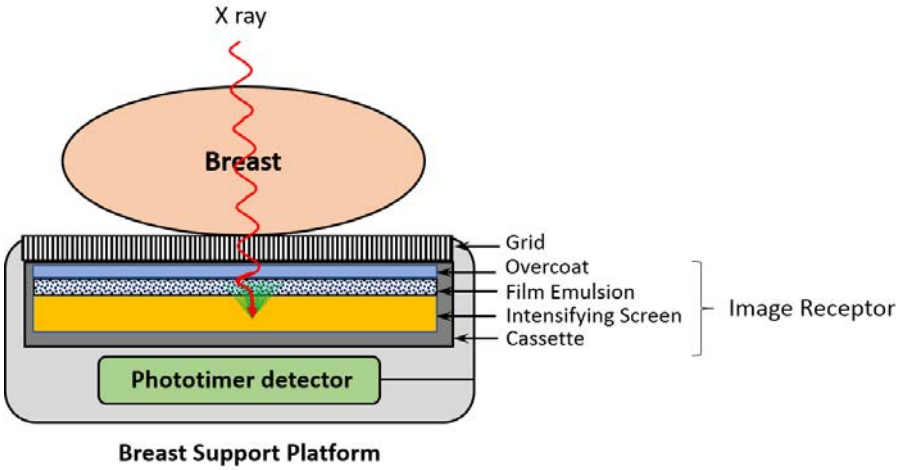

FIG. 37. Construction of a mammographic screen-film system. A single emulsion-single screen is used in mammography to preserve high spatial resolution. The image receptor is positioned such that X rays travel through the cassette cover and film before interacting with the intensifying screen. As X rays are more likely to interact near the screen phosphor surface, which is closest to the film emulsion, this configuration reduces the distance between light photons and film emulsion and minimizes the diffusion path of the light to preserve high spatial resolution.

render a pattern of varying dark areas on the film. When placed on a brightly illuminated surface (of a viewing box) the light transmitted through the film forms the mammographic image that is viewed and interpreted by a radiologist.

In CRM, a fluorescent screen in a cassette is used as in an SFM set-up and no film is required. The construction of a CR imaging plate is shown in Fig. 37. Rather than the phosphor emitting the light during exposure, the phosphor is 'photostimulable' in that the energy from the absorbed X rays forms a pattern of trapped electrons in the phosphor, the density of electrons being proportional to the number of X rays absorbed. This latent image pattern is stored in the traps until the cassette and plate are moved to a reader (Fig. 38) where the latter is raster scanned by a fine red laser beam and the electrons are released from the traps to emit blue light. The intensity of the emitted light is recorded digitally and, when plotted versus the *x-y* coordinates of the point on the plate from which the light was emitted, produces the digital image.

In DDM systems, a detector is integrated into the mammography system. This detector absorbs the X rays transmitted by the breast, converts their energy into a pattern of electrons, records the associated signal on very small

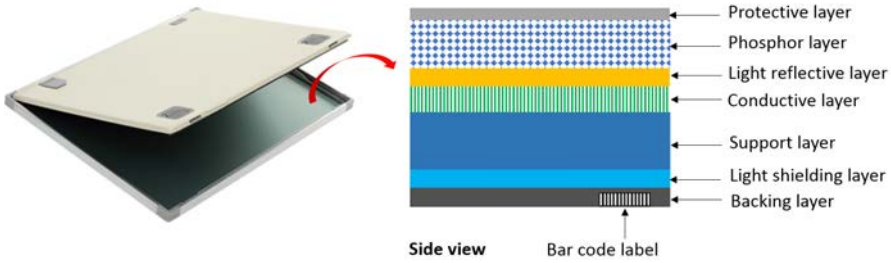

FIG. 38. Construction of a CR imaging plate [28, 97]. The photostimulable storage phosphor is doped with a small number of impurities (e.g. europium, Eu), which alter the physical properties of its crystalline structure. When X ray energy is absorbed by the phosphor, the absorbed energy excites electrons associated with the europium atoms and enables them to enter the conduction band. Some electrons return immediately to the valence band, but others remain 'trapped' in the forbidden zone (so-called F-centre) between the two bands. The F-centre traps these electrons in a higher energy, metastable state where they can remain for days to weeks, with some fading over time. The number of trapped electrons per area unit is proportional to the amount of radiation incident at each location during the exposure [32].

discrete elements of the detector and allows readout along wires in the detector for digitization.

Even though SFM, CRM and DDM systems are the three broad categories that represent different technologies of imaging, it has to be highlighted that even within each category one can identify large variations in the technical design (e.g. powder versus needle detectors for CRM, direct versus indirect X ray conversion in DDM). Selecting the proper technology requires care, as the implications for the resulting image quality, radiation dose and cost of the equipment can be significant.

Film based imaging was the reference standard for many years. It is relatively inexpensive, but it is now gradually being replaced by digital technologies because it can overcome inherent limitations of film based technologies, including the necessity of film processing and inability to control the brightness, contrast and other image display properties while viewing images. The advantages and limitations of film compared to digital imaging are summarized in Table 8.

An important factor that distinguishes the performance of SFM, CRM and DDM systems is associated with point to point non-uniformities in the image that are unrelated to the breast, such as spatial variations in the X ray beam intensity or variations in the sensitivity of the detector. These are spatial variations that are constant, at least over periods of days or more.

In CRM, these variations will be displayed in the image and can reduce its quality. They are often termed 'fixed pattern noise' (e.g. screen artefacts).

TABLE 8. ADVANTAGES AND LIMITATIONS OF FILM BASED IMAGING AND DIGITAL IMAGING

	Advantages	Limitations
Film based imaging	— Low cost — High spatial resolution — Less sensitive to scattered radiation — Multiple sizes of image receptors — Ease of display — Well established technique	— Requires special rooms (darkroom) and physical storage of films pre- and post-irradiation — Requires the use of chemicals, wet processing, well controlled processing conditions and special drainage or waste facilities — Limited dynamic range — Characteristics of recorded image (e.g. contrast, brightness) cannot be adjusted — Cannot be transmitted without the loss of information through scanning — May require a higher dose to the breast than digital systems
Digital imaging	— Efficient information dissemination and increased access to images — Wider dynamic range — Improved reliability, error free retrieval of images without information loss — Improved workflow and patient throughput — Potential for multimodality, composite imaging — Simultaneous transmission and display of images to multiple locations — Image manipulation and postprocessing, feature extraction and enhancement	— High initial cost — Generally poorer limiting spatial resolution compared to screen-film — Susceptible to artefacts due to the imaging plate (for CRM) or image processing algorithms — Increased sensitivity to scattered radiation — Loss of instantaneous feedback on over- or underexposure — Requires some basic knowledge of digital image processing and viewing — Requires IT support for interconnectivity

TABLE 8. ADVANTAGES AND LIMITATIONS OF FILM BASED IMAGING AND DIGITAL IMAGING (cont.)

Advantages	Limitations
— Immediately available to authorized viewers after image acquisition (for DDM) or reading (for CRM) — Eliminates environmental problems caused by film based imaging — Eliminates darkrooms and physical storage space	

In DDM systems they can be removed by imaging a uniform field (such as a slab of plastic) and performing corrections on the recorded image to make it virtually uniform. The 'mask' or 'gain map' describing those corrections is stored digitally and used to correct all subsequent images, essentially removing the fixed pattern noise. The manufacturers specify the number of non-uniformities that can be corrected. Because the plates in CRM are not integral to the system but are removed for processing and interchanged, it is much more complex to perform such a correction on CRM images and this is not done on commercial systems. Therefore, CRM images are much more subject to the effects of fixed pattern noise.

CRM systems are considered a relatively inexpensive solution (see Table 7) compared to DDM systems. CRM technology is often considered to be a natural step when moving away from film technologies, as it offers increased flexibility on the choice or reuse of X ray equipment and the ability to be used with more than one X ray system.

Nevertheless, the following considerations should be kept in mind:

— The ease of transition is sometimes misleading and, if an effective intercommunication between the X ray and CRM is not provided, as is sometimes the case, this can lead to misuse and suboptimal performance.
— The spatial resolution is limited for the demanding application of mammography.
— The efficiency of using the radiation to form the image is limited: radiation doses (and exposure times) are higher than in DDM systems and occasionally even higher than in SFM systems [26, 27].

— Phosphor plates have a limited lifespan, and their performance has to be evaluated frequently.
— The need to physically move imaging plates is labour intensive, reduces productivity and causes wear and tear.

It ought to be mentioned, however, that retrofit detectors may be a cost effective alternative to CR plate detectors: they can be used in combination with existing X ray devices and have an intrinsic quality compatible with typical digital technology detectors [12].

DDM systems offer all of the digital advantages already described as well as improved spatial resolution compared to CRM. They efficiently detect incident radiation, offering significantly lower doses compared to SFM and CRM systems. However, they are more expensive, requiring substantial capital investment.

The need for proper implementation, use and maintenance of a mammography imaging system cannot be highlighted enough. Poorly installed, maintained or supervised systems pose obvious problems. However, the probability and extent of these problems increases when:

— The system has increased complexity and handling needs, such as in the case of film processing.
— The system is composed of disparate components that are not properly matched or adjusted to form an optimized configuration. This could occur, for example, when an existing mammography machine is ‘upgraded’ to digital with the procurement of a CRM system and cassettes without proper re-commissioning and maintenance.

II.3. DIGITAL BREAST TOMOSYNTHESIS

DBT is an X ray technique in which the X ray tube moves over a limited angle (between ±7° and ±30°) around the breast to acquire multiple projections (typically 9 to 25) [28] (Fig. 39) which are then used to reconstruct a 3-D stack of planar ‘image slices’. This allows radiologists to view breast images in planes parallel to the detector and overcomes much of the tissue overlap that is characteristic of normal projection imaging. The benefit of DBT in comparison to 2-D mammography has been demonstrated for the detection of masses, while its performance in detecting microcalcifications is a topic of ongoing investigation [98–100].

DBT was approved by the US Food and Drug Administration (FDA) in 2011 as a diagnostic technique and for screening in adjunct to DDM systems. More recently it was also approved as a stand-alone technique. Several clinical

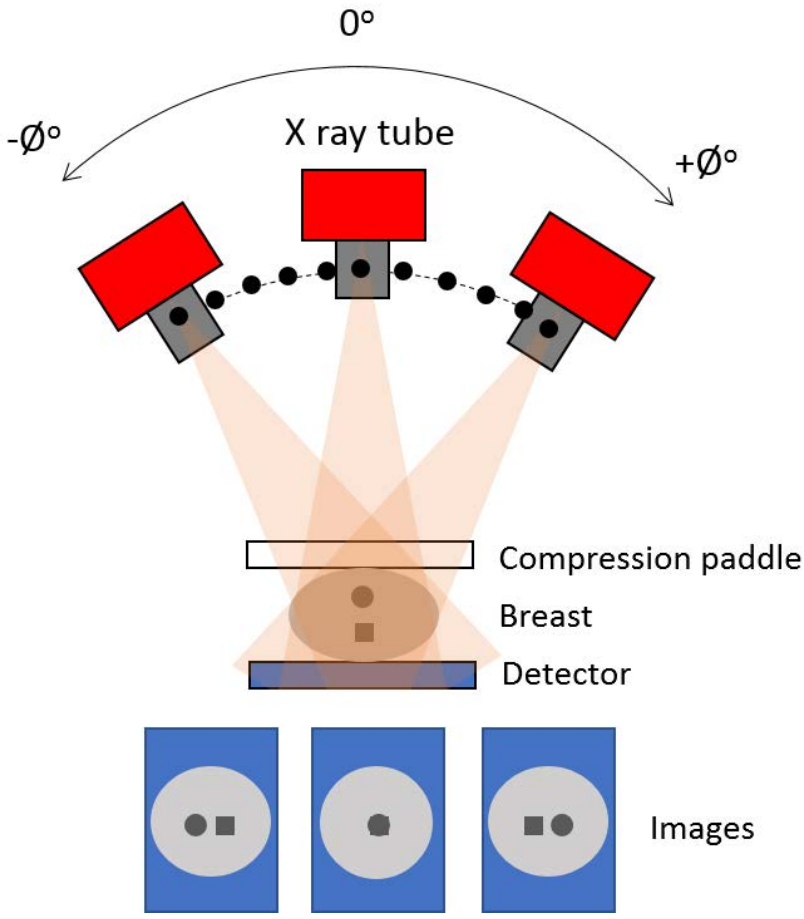

FIG. 39. Basic principle of DBT. The X ray tube moves over a limited angle (–Ø° to +Ø°) around the breast to acquire multiple projections. These projections are then reconstructed to produce a series of images in closely spaced focal planes parallel to the detector to overcome the issue of tissue overlapping in conventional 2-D mammography.

trials have also evaluated this new modality within the framework of screening. These found increases in cancer detection of typically 30%, as well as a decrease in false positive recall rate. Today, however, there is not yet a proven impact on the interval cancer rate or on mortality, probably due to limited data so far.

The combined application of mammography and DBT increases the dose to the breast for a complete exam by up to 160%. Other practical issues influencing the uptake of DBT for screening are the increased reading time required of a radiologist, the large data volumes affecting speed of access and

archiving and the equipment costs. A technical feature that may address some of these issues is synthetic 2-D imaging: these images are calculated from the DBT data and provide a 2-D overview similar to conventional mammograms. The algorithms for performing synthetic 2-D imaging continue to evolve but, at the time of writing, there have been mixed experiences as to the acceptability of discontinuing the use of 2-D DDM in conjunction with DBT in favour of DBT with a synthetic 2-D image.

II.4. CONTRAST-ENHANCED DIGITAL MAMMOGRAPHY

CEDM is an imaging method designed to allow visualization of iodinated contrast medium, intravenously injected to the patient. This demonstrates the leakage occurring from microvasculature to the interstitial space due to tumour angiogenesis. The technique is based on the subtraction of two images to isolate the iodine signal.

Most commonly a 'dual energy' technique is used (also called spectral mammography by one manufacturer), where the two images of the breast after contrast medium administration are acquired with different spectra, one rich in photons of energy below the K absorption energy edge of iodine at 33.4 keV and the other with photons predominantly above that energy. After acquisition, the images are processed to transform the original pixel values into their natural logarithms (base e). The two transformed images are then subtracted. Subtraction of the log images is essentially equivalent to dividing the original images by one another. This tends to remove the dependence of the result on factors such as the intensity of the radiation beam, scattered radiation, etc.

CEDM provides enhanced visualization of the distribution contrast medium leakage, corresponding to the lesion. The clinical motivation for the technique is the association between contrast medium diffusion into the extravascular medium, possibly observed after the subtraction, and the occurrence of angiogenesis, which could be attributed to tumour progression. CEDM has shown increased sensitivity but lower specificity than mammography. It is less expensive than MRI and its role compared to that of breast MRI is a topic of investigation [101, 102]. Figure 40 compares the appearance of images from CEDM and MRI.

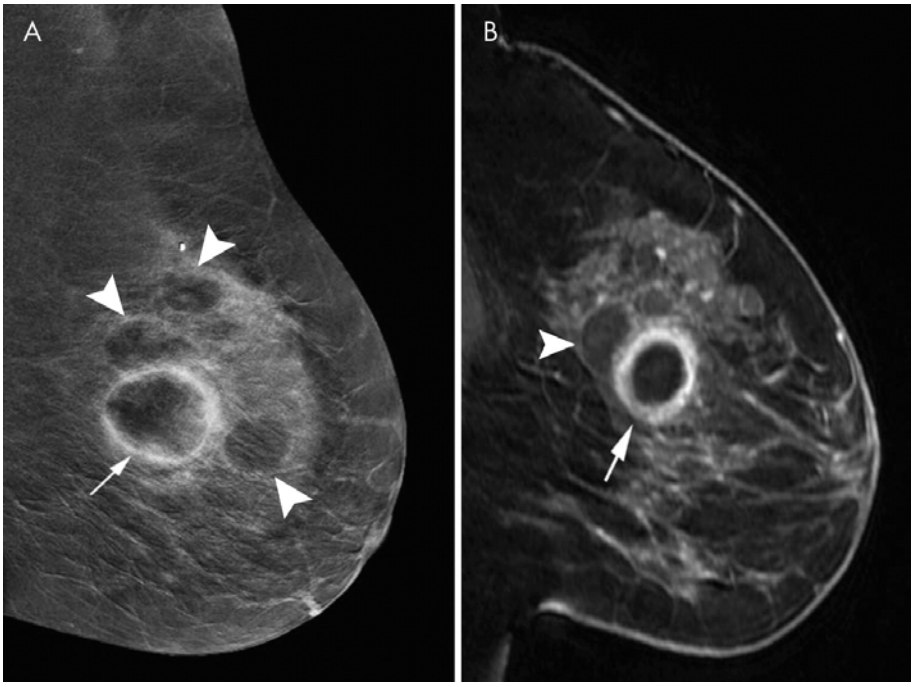

FIG. 40. Images of a 44-year-old woman's left breast presenting with a palpable abnormality illustrate that cysts have different appearances in (a) CEDM compared with (b) contrast-enhanced fat-suppressed T1-weighted breast MRI. In both images, simple cysts (at the arrowheads) can be identified as well defined masses showing no or negative enhancement. Inflamed cysts (at the arrows) may show a thickened and often slightly irregular wall, which enhances after contrast material administration. (Reprinted with permission from Jochelson MS, Lobbes MB. [103].)

Appendix III

OTHER BREAST IMAGING MODALITIES

There are several imaging modalities available for the evaluation of breast disease. Of these, the roles of mammography, ultrasound and breast MRI have been clearly established. DBT is becoming more widely used in some jurisdictions, but its contribution, as well as those of CEDM, breast CT and nuclear medicine studies such as PET or positron emission mammography are still under clinical evaluation. One of the challenges in current practice is to identify the appropriate role (if any) of these modalities for breast cancer imaging. At a first level, the use of a modality ought to be determined first by the added diagnostic value provided by that modality as justified by scientific evidence from well conducted studies and then by the financial ability to support its use. Other imaging modalities have also been suggested for breast cancer imaging because they do not require the breast to be exposed to ionizing radiation. These include thermography, the imaging of infrared energy emitted by the breast, and electrical impedance imaging.

Among all these modalities, mammography is the only technique proven to reduce breast cancer mortality when used for routine screening of asymptomatic women [76]. Justification for screening with modalities using ionizing radiation needs to be made carefully. Furthermore, the risks associated with the radiation ought to not be overestimated. In their study, Yaffe et al. calculated the ratio between cancers detected in the screening and radiation induced cancers using different screening regimens in terms of frequency of imaging and age ranges in Canada [104]. Even for yearly mammograms from the age of 40 to 75, a net benefit is estimated. Currently, doses received in DBT are similar to those discussed in their study, and the detection rates have been proven to be better than what is achieved in DDM systems today. The next candidates of screening techniques are CEDM and breast CT. MRI is more expensive and less widely available but has a role in the high risk population [105]. Ultrasound is also considered a complementary examination or for particular groups, such as women with dense breasts. Nuclear medicine techniques have not yet been tested for screening purposes.

III.1. ULTRASOUND

Ultrasound is a safe, reliable and non-invasive modality that does not use ionizing radiation to evaluate the breast. It is an essential imaging modality

for evaluation and management of the patient with breast symptoms or mammographic abnormalities. Ultrasound is usually adjunct and complementary to mammography and the clinical examination, but in a young patient presenting with symptoms, ultrasound may be the initial or sole imaging procedure.

The main indications for breast ultrasound include an assessment of palpable breast abnormality, differentiation between cystic and solid lesions, evaluation of a palpable lesion in a mammographically dense breast, further evaluation of lesions detected at mammography or mammographic asymmetry, an evaluation after breast cancer treatment, assessment of axillary lymph nodes and guidance for interventional procedures.

Several studies have reported good results in ultrasound screening in women with dense breasts, who had negative mammograms yet some clinical indication. Here, ultrasound showed an incremental cancer detection rate of 2.8 to 4.6 cancers per 1000 women. Nevertheless, in studies comparing MRI, mammography and ultrasound prospectively for breast cancer screening in women at high risk, ultrasound consistently performs worse for cancer detection and specificity than the other two modalities and does not increase cancer detection beyond that achieved when both mammography and MRI are used. Ultrasound is generally acknowledged to be a highly operator dependent modality that requires a skilled practitioner, state of the art equipment and a longer examination time per patient.

III.2. MAGNETIC RESONANCE IMAGING

MRI is an excellent imaging technique in the diagnosis of breast disease due to its sensitivity to subtle tissue changes. It does not involve ionizing radiation and can be repeated several times and performed in young and pregnant patients without the risks related to radiation dose, although there may be risks associated with foetal exposure to the gadolinium contrast agent used with MRI. Breast MRI is usually performed with the injection of contrast agents that show the perfusion patterns of the breast cancers. Then 3-D imaging is applied. A more recent evolution, in full exploration, is diffusion weighted MRI.

MRI of the breast is a useful tool for the detection and characterization of breast disease, assessment of the local extent of disease, evaluation of treatment response and guidance for biopsy and localization. In addition, MRI is used to clarify indeterminate cases at mammography and ultrasound, as well as to detect breast cancer for people at high risk and in the younger population. In the latter instances, annual screening with breast MRI is recommended in women with the following risk factors: carriers of so-called BRCA (BReast CAncer gene) mutation, untested first-degree relatives of a BRCA carrier, women with a

lifetime 20% or greater risk (as defined by the so-called BRCAPRO or other risk models), women with a history of radiation to the chest when aged 10–30 years.

Although an excellent imaging modality, MRI ought not to replace mammography and ultrasound in the initial assessment of breast disease. Several studies showed MRI to be more sensitive than other imaging techniques in detecting early breast cancer in women who are at high risk, whether symptomatic or asymptomatic, but specificity is more variable.

There have been efforts to develop 'abbreviated' methods to acquire breast MRI exams more quickly to reduce cost and make the examination more practical for screening [106].

Disadvantages of MRI include:

— High cost of the equipment, the facility preparation and the examination itself;
— Increased risk for the patient due to the contrast agents used;
— Limited access to MRI equipment;
— Lower specificity than mammography (i.e. greater likelihood detecting non-negligible false positive findings that can lead to additional diagnostic procedures, costs and psychological burden to the patient).

III.3. NUCLEAR MEDICINE TECHNIQUES

Although traditional nuclear medicine imaging (mammoscintigraphy with ^{99m}Tc-Sestamibi) plays important roles in the clinical management of breast cancer patients regarding treatment and subsequent follow-up, its role in screening and the initial approach to diagnosis is limited. The small field of view PET scanners dedicated to the breast are called positron emission mammography systems and use ^{18}F-fluoro-2-deoxy-D-glucose (^{18}F-FDG) as the metabolic tracer. The imaging performance of this equipment is even better than that of gamma cameras dedicated to breast imaging but, so far, their use is limited to very few centres worldwide.

PET/CT with ^{18}F-FDG is currently not recommended for patients with early stage breast cancer without evidence of regional nodal spread, unless its use is indicated as related to symptoms or clinical findings. The use of ^{18}F-FDG PET/CT is, instead, currently recommended for suspected recurrent breast cancer as well as for assessing response to therapy in breast cancer patients with known metastases.

The radionuclide studies in patients with breast cancer are also used in radiation guided surgery, particularly radiation guided sentinel lymph node biopsy, which is indicated for staging the axilla in patients with early breast

cancer and with a clinically negative examination of the axilla. The reliability of sentinel lymph node biopsy increases with more advanced imaging equipment (e.g. single photon emission computed tomography/CT).

III.4. DEDICATED BREAST COMPUTED TOMOGRAPHY

One of the earliest systems introduced for CT was a dedicated breast system [107, 108]. Although the technology at the time was very primitive, with large detector elements and thick (5–10 mm) slices, the technology was sufficiently sensitive to demonstrate lesions in the breast. These systems showed substantially greater sensitivity when the subject received an injection of an iodinated contrast medium. Little further development of breast CT occurred until recently, when academic clinical systems were developed at the University of Rochester [109, 110] and at the University of California Davis [111, 112]. Unlike the original systems, which were based on single-slice detector arrays and a thin fan-beam of X rays, these systems used 2-D digital detectors developed for DDM and a cone beam X ray geometry. Therefore, they were referred to as cone beam CT systems. Despite the greater susceptibility to detection of X rays scattered in the breast, these systems showed remarkable contrast sensitivity and again performed particularly well at depicting and allowing characterization of breast lesions when iodine contrast was used, in which case the procedure was referred to as contrast-enhanced cone beam CT [113]. In a more recent implementation, spiral scanning and photon counting detectors are also used [114].

Appendix IV

MAMMOGRAPHY EQUIPMENT PERFORMANCE

IV.1. PHYSICO-TECHNICAL AND DOSIMETRIC EVALUATION

This appendix presents papers and studies that illustrate the relationship between equipment performance and mammography process for the main forms of mammography technology, namely SFM, CRM and DDM (discussed in Appendix II). The publications outlined below report on evaluations of physico-technical parameters appropriate to assess the equipment's performance. Some of the physical parameters commonly used to characterize digital systems are also discussed.

Monnin et al. in 2005 [115] performed physics tests on SFM and CRM systems, which included noise equivalent quanta (known as NEQ), detective quantum efficiency (DQE), modulation transfer function (MTF) and noise power spectrum. They found that CRM had reduced spatial resolution and increased noise characteristics compared to SFM.

In 2007, a further work by Monnin et al. [116] compared the digital image quality parameters of DQE, MTF and normalized noise power spectrum at different radiation doses in DDM and CRM systems. They concluded that DDM had higher MTF and DQE (i.e. better intrinsic imaging performance capabilities) than CRM in the mid to high spatial frequencies (corresponding to fine and very fine detail in images).

Image quality and dose of two CRM and six DDM systems from different vendors were evaluated within the Flemish mammography screening programme in 2009 [117]. In general, the DDM systems passed the European acceptance criteria more easily than the CRM systems did. European researchers reported in 2012 on measurements of inferior detection of calcifications when inspecting CRM images compared with DDM images [6]. Belgian researchers reported on measurements of inferior sharpness in the depiction of small calcifications using CRM [118]. A study in the United Kingdom found that it was possible to compensate for part of the reduction in image quality by increasing CRM radiation doses by about 60% to a factor of two or more compared to doses used with SFM or DDM [27].

In 2013, a survey of mammography equipment used by the breast screening programme in Ontario, Canada, (32 SFM, 43 CRM and 148 DDM units) evaluated the parameters MTF, noise equivalent quanta, SDNR and detectability index, among others. Results showed that the performance of CRM was

substantially lower compared to DDM, and that CRM and SFM shared similar artefact problems (dust and fibre-like images) [96].

In 2013, Belgian researchers compared the technical performance parameters of 25 CRM and 37 DDM systems. Imaging metric results were similar for both modalities, but CRM imparted 60% higher doses than DDM [26].

IV.2. EQUIPMENT PERFORMANCE IN THE CLINICAL ENVIRONMENT

The technical performance of clinical mammography units mainly considers image quality and dose. In addition to the intrinsic physico-technical differences among technologies, performance often depends strongly on the specific conditions encountered at the site where it functions. This can be particularly critical when QA regulations do not exist or are not enforced. Many factors can explain the specific performance of a clinical system, such as the level of maintenance, existence (or lack) of QC tests and the availability of maintenance service and well trained personnel, among many others. The following examples compare the performance of mammography systems in clinical use in several countries.

In Poland, in 2011, doses from single exposures were measured for five CRM and four DDM units [119]. Individual doses varied over a factor of 30 in CRM and a factor of 16 in DDM.

In 2016, image quality was evaluated for 47 systems in Poland, including SFM, CRM and DDM [120]. Results showed a significantly higher visibility of the ACR phantom objects in the DDM images. The average dose in a CRM system was about 80% higher than the average for a DDM system. One of the conclusions was the need to implement standard methods of optimization to reduce individual doses to the minimum that is consistent with good image quality. SFM could deliver images as good as CRM at a much lower dose, if proper equipment maintenance was ensured. It was concluded that only DDM could provide good image quality and low dose simultaneously [120].

In Greece, in 2011, 26 CRM and 26 DDM units were studied with respect to dose and image quality using the ACR phantom. Results showed that 98% of the systems complied with the phantom image score needs, but large differences in dose and quality metrics were observed among different facilities. This finding signalled the need for exposure optimization procedures and adjustments of the AEC [121].

An evaluation of mammography image quality and dose was carried out in seven Latin American countries in 2017 under the auspices of the IAEA. MGD, SDNR and MTF were measured in 24 health services equipped with a total of 11

DDM and 13 CRM systems. Results showed severe problems in the performance of the CRM systems, where only 38% of the units produced acceptable levels of SDNR for a standard 4.5 cm thick polymethyl methacrylate (PMMA) phantom. On the other hand, DDM systems performed within acceptable levels, even for an 8 cm thick phantom. Most of the participating facilities were not familiar with MTF measurements and did not report these results. Several regional problems, such as lack of familiarity with digital image analysis and insufficient training, were reported [122].

In 2015, a study in the Brazilian state of Minas Gerais evaluated dose and image quality using the contrast detail mammography (CDMAM) phantom, contrast to noise ratio and image noise for 68 digital systems (65 CRM and 3 DDM) [123]. Of the CRM units, 10% complied with the contrast to noise ratio needs and 31% complied with the noise acceptance criteria, which indicated the desired dominance of quantum noise over electronic or structured noise in images. Of the evaluated images, 65% were of good quality. A previous study with SFM systems at the same location had shown 46% of images met quality compliance [124]. The authors discussed the possible causes for this poor performance of CRM units, identifying the intrinsic limitations of CRM and lack of integration of maintenance for system components, including the X ray unit and the CR plates reader.

In Mexico, mammography image quality scores, measured using the ACR phantom, and radiation doses have been investigated for both CRM and DDM technology. In 2014, 65 facilities with CRM systems in Mexico City and surroundings were evaluated in terms of ACR phantom score and MGD [125]. Results showed that 79% of the images presented artefacts; compensation was made for the decrease in CR plate sensitivity over time by using higher exposures, and MGDs above 3 mGy were measured in 26% of the systems. Only 1.5% of the images scored above the threshold of 10 visible objects, which was deemed to be an achievable score in the ACR test phantom images [126]. An independent analysis investigated new DDM systems in 36 facilities distributed over the country [125]. All units passed the criteria for signal to noise ratio, contrast to noise ratio, ACR phantom scores and dosimetry. The authors interpreted the poorer performance of CRM with respect to the new DDM system because of the lack of technical maintenance and QC tests. Other problems they identified were the low numbers of radiologists, medical radiation technologists and CQMPs specialized in mammography imaging in the country.

Furthermore, again in Mexico, an evaluation of 20 CRM systems operated by the Secretary of Health in 13 Mexican states (17% of the Secretary of Health CRM systems in the country, performing about 64 000 screening studies yearly) measured parameters of image quality and MGD for 2–7 cm thick PMMA plates [127]. The investigation included over 30 tests and phosphor plates and

CR plate readers from several vendors. The percentage of systems complying with international recommendations was generally low. Only half of the units delivered acceptable MGD doses for acrylic plates with a range of thicknesses and only 7% of the units reached the acceptable threshold dose for the CDMAM 0.1 mm diameter gold disc (see Appendix V for more details of this test). Three quarters of the units showed unacceptable image quality in terms of the CDMAM thresholds. All units showed artefacts on images, and only 5% complied with AEC breast thickness compensation needs. The study's authors concluded that the complex CRM technology made it difficult to operate under the optimum technical conditions for mammography screening. In particular, the required coordination between maintenance services on the X ray unit and on the CR plates reader at the commissioning of the CR plates reader and afterwards was not implemented in any of the evaluated services. This probably explains the generalized failure of 'mixed' QC tests, such as AEC breast thickness compensation, where the operation of the mammography unit needs to be optimized on the basis of results measured in the images. The presence of artefacts in all the units and the failure to comply with the MGD limit (3 mGy) for a 4.5 cm thick phantom established by the national regulations are interpreted as a consequence of the lack of appropriate QAP in the mammography services, the absence of CQMPs and a deficient enforcement of regulations by the appropriate agency.

Appendix V

QUALITY MANAGEMENT

Quality assurance in mammography refers to a set of measures designed to ensure that the entire process is carried out with appropriate quality so that the imaging goals (accurate earlier detection of cancer) are carried out as effectively as possible with the least harm. Mammography is a complex system of activities that, like a chain, is only as strong as its weakest link. Therefore, all aspects of the system ought to ideally function properly, including the management of patient workflow, positioning and compression of the breast, image acquisition (by medical radiation technologist), image interpretation and recommendations (by radiologist), record keeping, informing the patient and referrer of results, follow-up procedures, testing of equipment performance and radiation doses (by CQMP), optimization of procedures and setting of dose reference levels (by CQMP) and sanitization of the imaging environment.

The need for QA processes and quality improvement in diagnostic radiology is driven by several factors. These include: the importance of radiological diagnosis to patient management within the health care environment, the high cost of radiological equipment, the ever-increasing complexity of examination equipment and examination procedures due to technical advances and concerns regarding increased radiation doses to the breast due to non-optimized protocols and equipment performance. The importance of these matters has been acknowledged within Europe through a directive of the Council of the European Union [128]. We have demonstrated in Appendix IV how, when the performance of technology is not optimized due to its design, lack of maintenance or improper calibration, imaging performance is measurably diminished, and this can lead to poorer imaging outcomes such as missed cancers or increased false positive rates.

Technically appropriate image quality always needs to be the objective. There are different phases in this task: When a device is accepted, its quality ought to be verified with typical QC protocols. It is also necessary to ensure that the equipment strictly complies with the technical specifications established in the purchase agreement for the system and that the equipment has been installed by appropriately trained engineers. Systems can also be compared to other similar systems, and baseline values have to be established. This phase is followed by a daily evaluation of technical image quality and dose and other periodic tests by CQMPs. To achieve and maintain high quality mammography, it is necessary to set up a QAP for the mammography service. The facility ought to work with the assistance of a CQMP and can benefit from the considerable material on methods

used in QC in Refs [2, 5, 129]. In many countries, the introduction of a QAP has boosted the quality of mammograms [130].

V.1. QUALITY CONTROL (LOCAL AND REMOTE TESTING)

It is important for mammographic image quality to always be maintained as close to an optimal state as possible. This requires the coordinated effort of the whole team including both clinical and technical personnel. Radiologists need to report to the medical radiation technologist or CQMP any technical problems, artefacts, etc. that are observed in the mammograms. Medical radiation technologists interact with images and equipment constantly and, therefore, have a unique role in the verification of daily quality.

A local QAP ought to be established. If this is not possible or, especially when local resources are limited, it may be preferable for the facility to conduct QC of the physical and technical aspects through a remote programme operated from a centre of expertise. In either case, it is necessary for the medical radiation technologists on site to perform a few periodic (daily or weekly) technical measurements to ensure that consistent, high quality is maintained. If there are multiple medical radiation technologists present, it is preferable that only one or two of them be responsible for QC testing, as this allows them to develop and maintain expertise, provides continuity and minimizes user dependence on results with visual assessment tests.

An example of a remotely controlled programme is the one developed for the DMIST trial in the USA, of which the results have been published [45]. Some guideline documents, such as the European Guidelines, also recommend a centrally supervised QAP [6]. In some European countries, such daily QAPs have been implemented for both SFM and digital systems. The number of technical issues found justifies this effort [131]. In the recent IAEA Human Health Series Report 39, the needs and challenges of periodic QC tests were recognized, especially for regions with limited medical physics availability [132]. An expert team subsequently developed a phantom and evaluation software for automated QC data retrieval. In addition, monitoring and logging software was developed. The phantom suggested for mammography consists of two homogeneous plates of 2 cm thick PMMA, a copper insert for MTF calculation and a piece of 1 cm × 1 cm aluminium 0.2 mm thick for contrast evaluation (Fig. 41). A software tool calculates signal to noise ratio, SDNR, MTF, noise power and a specific detectability index, and generates an output that can be used for follow-up over time [115].

For SFM systems, daily QC is required to guarantee proper film development. This is especially the case if film with high gradients is used. Next to

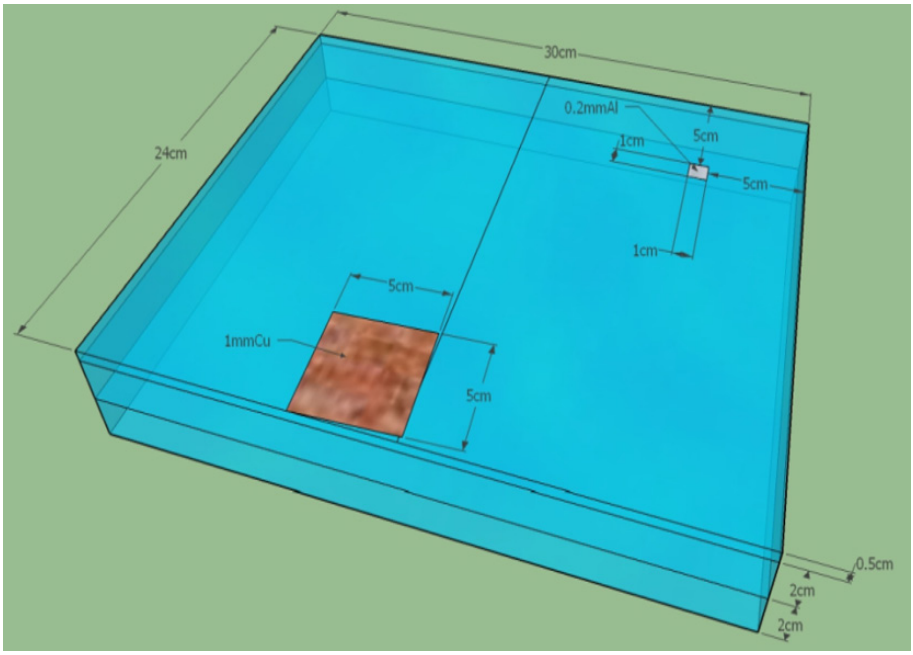

FIG. 41. Sample quality control phantom developed for remote and automated quality control in mammography (reproduced from Ref. [132]).

properly managed film developing and fixing products, proper film development timing and developer temperature are crucial. In most cases the development conditions for mammography films are different from those for general radiology films and, therefore, monitoring the processing of mammography film requires specialized QC testing.

For DDM systems, when image interpretation is carried out from a computer monitor, there is no longer a need for film-related QC. Quality control for DDM systems focuses on the electromechanical performance of the X ray unit, performance of the AEC, tube output, beam quality, MGD, image receptor and image quality, and visualization conditions including proper calibration and performance of the viewing monitors. Basic QC protocols are specified by the manufacturers of the DDM systems.

For CRM systems, there may be increased complexity because the X ray production components, the detector and the image processing and display may come from different manufacturers. CRM systems also require significant effort in managing individual cassettes and the monitoring and minimization of system artefacts.

V.2. SPECIFICATIONS OF SYSTEMS (BENCHMARK DATA ON SYSTEMS)

At acceptance, the safety and mechanical stability of the X ray device, the beam qualities, the characteristics of the detector, the AEC, the dose received by the breast and image quality, and the image reading conditions need to be verified. Several protocols list tests and limiting values in great detail [2, 5, 6]. Clinical image processing evaluation is normally performed by the radiological team. While there are no established criteria in the literature, some guidelines can be found in the study by Boita et al. [133].

Most reports in the literature describe specifications of SFM and DDM systems in detail, with a lack of data on CRM systems. In the following subsections, we provide additional details on CRM systems.

V.2.1. Characterization of a digital detector

This section provides a general overview of the types of measurements that would be performed for a technical characterization of a DR detector system, such as sharpness, noise, DQE, etc. For detailed methods, the reader could refer to publications such as the one by Marshal et al. [134].

Digital mammograms are often available in two versions. The raw or 'for processing' image (a term used in the DICOM nomenclature) is closely related to the signal that is generated by the detector. The processed or 'for presentation' image (DICOM) may have had various transformations applied to it for better visualization of the mammograms. For QC testing purposes, CQMPs ought to attempt to require access to these unprocessed images, possibly as a requirement in purchase specifications. The measurement of detector characteristics requires access to 'for processing' images to ensure that the technical images can be linearized with dose. Most CR detectors do not produce pixel values that are linear with the dose but rather respond with a logarithmic or power law relationship. Linearization is nevertheless possible if the 'for processing' data are available. For images that have been linearized, noise power spectra can be obtained by analysing a series of flat-field images taken at dose levels of interest.

A typical approach for MTF calculation requires acquiring the image of an edge phantom. It is important that the pixel values not be saturated (i.e. they do not drop to the minimum level or reach the maximum). This may require manually setting the sensitivity level and range. Especially for CRM systems, the MTF can be different in the two directions — often referred to as the scan direction and the subscan direction. MTF curves need to be measured for both perpendicular directions. Noise power spectra, MTF and a quality factor can be combined to calculate the detector DQE, a sophisticated descriptor of detector performance.

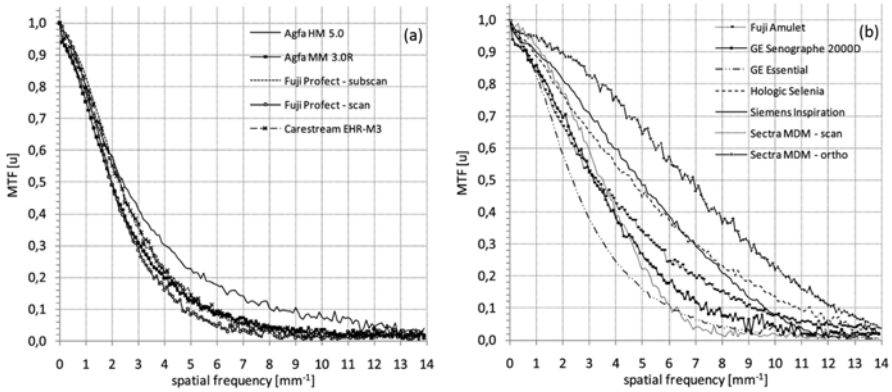

FIG. 42. MTF curves obtained from (a) CRM and (b) DDM systems. (Reproduced with permission from Marshall et al. [134].)

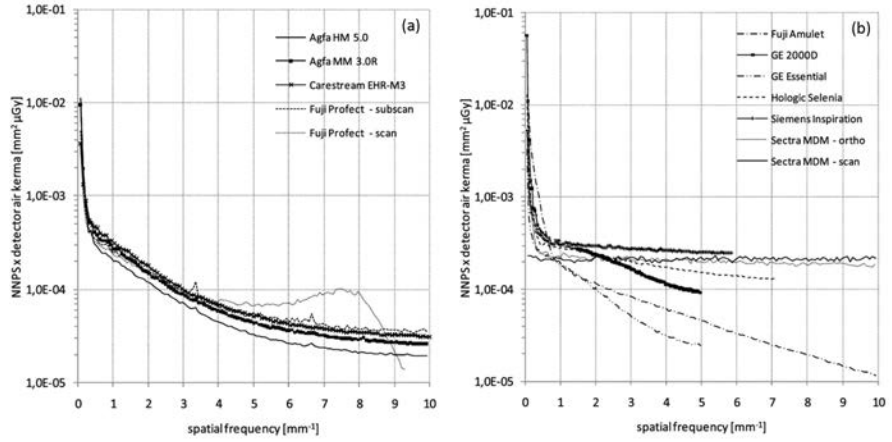

FIG. 43. Normalized noise power spectrum curves obtained using (a) CRM and (b) DDM systems. (Reproduced with permission from Marshall et al. [134].)

Examples of such measurements are reprinted from Marshall et al., with Figures 42–44 showing MTF, noise power spectrum and DQE, respectively, for common CRM and DDM systems [134].

Marshall et al. [134] showed that the performance of CRM technology is, in general, lower than that of DDM in terms of MTF and DQE. Within the group of CRM systems, there are also differences in performance, with those detector plates that employ a needle-like structure generally demonstrating better MTF characteristics (i.e. sharpness) than conventional powder CR plate

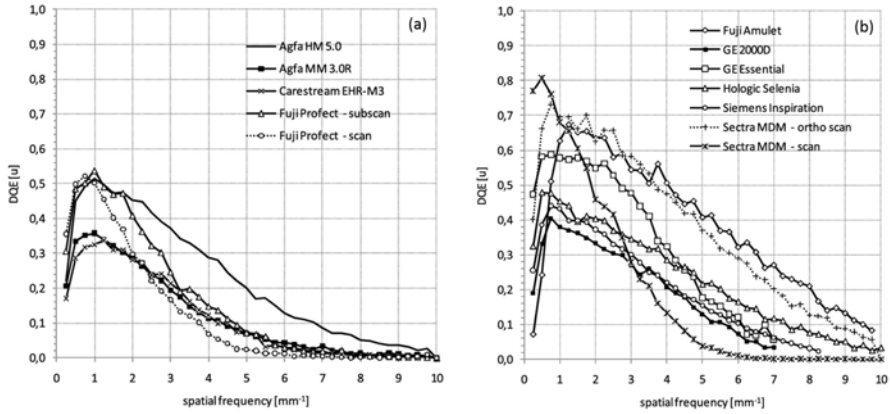

FIG. 44. DQE curves obtained using (a) CRM and (b) DDM systems. (Reproduced with permission from Marshall et al. [134].)

phosphors. Needle-type plates also appear to provide significantly better DQE than powder phosphors.

Yaffe et al. [96] compared CRM and DDM systems and found very similar results: the performance of CRM is in general lower than that of DDM systems. Exceptions may exist, especially when comparing the highest quality CRM systems with lower-end quality DDM systems or with systems operating at exposure levels that are too low. Bloomquist et al. [135] described the use of noise equivalent quanta measurements to characterize imaging performance.

Wigati et al. [136] performed a retrospective study to verify the robustness of MTF measurements and found this metric to be very stable. In the paper, typical values are provided that can be used for benchmarking.

V.2.2. CRM evaluation

As with screen-film cassettes, CRM systems use multiple cassettes. Because a mammographic examination consists of several mammograms that are viewed together, it is important that all cassettes have similar X ray attenuation. This can be tested in several ways: If the AEC is sufficiently stable, all cassettes can be imaged with the same flat-field test object under AEC. All exposure data (kV, mA and anode/filter) and output signal values ought to be very similar, with mAs values typically within 10% of the mean value. If the AEC is not sufficiently stable, manual exposures can be made with all the CR plates, and pixel values can then be compared. This test is especially important if cassettes of different batches are used. Similarly, unless consistency of attenuation has been validated,

cassettes from different vendors ought not be used together. For practical reasons, at least six cassettes ought to be available, to allow adequate throughput.

V.2.3. Dose and imaging performance of the system

There is substantial literature on the link between dose and imaging performance in digital imaging. As it is difficult to estimate clinical performance directly from measures such as the DQE, more direct methods can be implemented, such as phantoms with a detectability task. As an example, the contrast detail phantom (CDMAM, Artinis, the Netherlands) is often used to test performance. Following the EUREF protocol [6], the phantom is sandwiched between two PMMA plates each 2 cm thick. AEC is used to make 6 to 16 images. Six of these images could be read by a human observer; alternatively, images can be evaluated by a computer program [137]. The maximum thickness of a gold layer in the contrast detail pattern, which is required to detect a specific series of disc diameters, is determined from these acquisitions. The thinner the layer, the better the performance [138]. Most often, the threshold gold thickness for the smallest diameters is used as a surrogate for a direct sharpness test. The National Health Service in the United Kingdom has published comparative data for such analyses for the performance of SFM, CRM and DDM systems [139]. Rather than listing threshold thicknesses, the results of CDMAM acquisitions as a function of dose can be recalculated into the dose required to detect gold discs of a specific diameter with a 50% chance. An example is shown in Fig. 45 [139]. Limiting values were proposed when digital imaging was introduced: the values correspond to the 5% poorest SFM systems that were in use in quality controlled mammography around the year 2000 in different European Union countries.

The application of the performance test following the EUREF protocol leads to issues with some CRM systems [6]. The most critical test for a CRM system is to achieve proper performance for thicker breasts. The test prescribed in the protocol uses the SDNR as calculated from a small and thin sheet of aluminium on a PMMA block of set thickness. The protocol requires that the SDNR for a 7 cm PMMA simulation (representing a 90 mm thick compressed breast) ought to not be lower than 90% of the SDNR that would be needed to just achieve the limiting values of the threshold thickness at 5 cm PMMA. Some CRM systems cannot achieve the required SDNR at 7 cm PMMA within the set dose limits. Occasionally, the exposure time to reach the high doses also becomes very long and would not be clinically acceptable.

In the absence of a CDMAM phantom and analysis method, the SDNR values as printed in the IAEA Human Health Series 17 (Table 9) can be used as a guide to typical values for systems with sufficient performance [2]. An alternative is the use of calculated detectability indices, such as those worked out

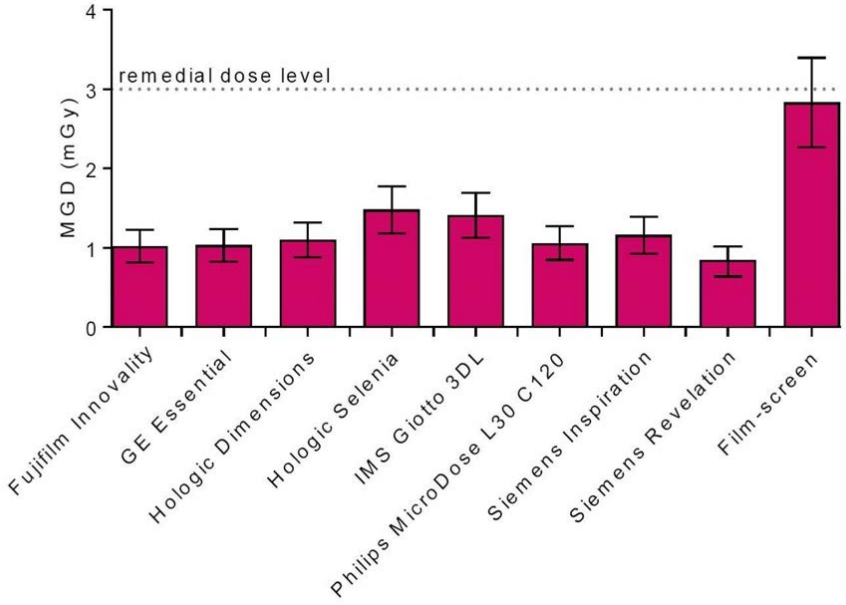

FIG. 45. Sample overview of the MGD to the 60 mm PMMA stack to reach the achievable limit of the 0.1 mm gold disc. Adapted from the United Kingdom National Health Service [139].

and applied on a large range of systems by Monnin et al. [115] and robustness tests described by Bloomquist et al. [135].

In terms of breast dosimetry, the AAPM has recently formed an official task group (TG282) [140] to develop a new model with corresponding methodology to estimate the breast average glandular dose (AGD) or MGD from standard mammography, contrast-enhanced mammography and breast tomosynthesis [141]. The mission of this task group is to replace the current disparate methods of AGD estimation used in the USA, Europe and the rest of the world with a single new model and method. The developed method will include the definitions of a reference air kerma measurement procedure, reference breast representations and conversion factors to estimate AGD from the reference measurements. Recommendations regarding the use and limitations of different metrics such as reference model AGD and patient model AGD will also be included.

Extracted from Table 13 in the IAEA HHS 17 document [2].

TABLE 9. ACCEPTABLE AND ACHIEVABLE LIMITS OF PMMA THICKNESS IN VARIOUS COMMERCIAL SYSTEMS

	PMMA thickness (mm)					
	20		45		70	
System	Acceptable	Achievable	Acceptable	Achievable	Acceptable	Achievable
Agfa CR (MM3.0)	13.8	20.1	12.4	18.0	10.8	15.8
Agfa CR (HM5.0)	10.2	15.0	8.9	13.0	8.0	11.7
Fuji CR	9.8	14.2	8.8	12.8	7.7	11.2
Fuji Amulet	6.1	8.7	5.5	7.8	4.8	6.8
GE 200D	8.9	12.9	7.9	11.5	6.9	10.0
GE DS	8.9	12.9	7.9	11.5	6.9	10.0
GE Essential	12.7	18.4	11.3	16.5	9.9	14.4
Hologic Selenia	4.8	7.0	4.3	6.3	3.8	5.5
IMS Giotto	7.8	11.3	7.0	10.1	6.1	8.8
Carestream CR (M2 plate)	9.5	13.9	8.5	12.5	7.5	10.9
Carestream CR (M3 plate)	11.7	17.0	10.2	14.8	9.1	13.3
Konica CR (RP-6M)	11.4	16.6	10.2	14.8	8.9	13.0
(RP-7M)	8.7	12.8	7.8	11.4	6.8	10.0
(CP-1M)	6.6	9.5	5.9	8.5	5.1	7.5

TABLE 9. ACCEPTABLE AND ACHIEVABLE LIMITS OF PMMA THICKNESS IN VARIOUS COMMERCIAL SYSTEMS (cont.)

	PMMA thickness (mm)					
	20		45		70	
System	Acceptable	Achievable	Acceptable	Achievable	Acceptable	Achievable
Planmed Nuance	6.3	9.1	5.0	7.2	4.3	6.2
Sectra D40	3.6	5.3	3.2	4.7	2.8	4.1
Sectra L30	3.6	5.3	3.2	4.7	2.8	4.1
Siemens Novation DR	5.1	7.4	4.5	6.6	4.0	5.8
Siemens Inspiration	4.4	6.3	3.9	5.7	3.4	5.0

* Source: NHSBSP technical evaluations published on www.cancer.screening.nhs.uk

APPENDIX VI

EDUCATION OF PROFESSIONALS IN MAMMOGRAPHY

Ensuring the quality of mammography is an important component in the management of breast cancer. The responsibility for the quality of a mammography programme is shared among the legal authorities, medical professionals, service engineers and vendors. Through close cooperation between regulators, radiologists, medical radiation technologists, medical physicists, service engineers and other support staff, it is possible to achieve an effective radiation protection programme and maintain a high quality mammography programme.

This section shows examples of qualifications and responsibilities set out by different countries for radiologists, medical radiation technologists and medical physicists involved in providing mammography services. Initial qualifications, continuing experience and education and re-establishing qualifications for different professions are discussed. Although personnel responsibilities are grouped separately, to obtain the optimal level of radiation safety and image quality, it is imperative that full cooperation exists among all concerned parties. Note that the professional development framework may vary among countries, and only a few randomly selected countries are presented as examples in this report.

VI.1. RADIOLOGIST

VI.1.1. Example: Canada

These are the needs as specified by the Canadian Association of Radiologists (CAR) [142]. Each facility ought to ideally complete an application questionnaire attesting to the qualifications of all mammography personnel. All interpreting and supervising radiologists, medical radiation technologists and CQMPs working in mammography need to ideally meet the CAR personnel qualifications. This includes part-time or temporary locum tenens staff. The CAR Mammography Accreditation Programme (MAP) ought to ideally be made aware of any changes made to personnel as soon as they occur. Failure to inform the CAR MAP can result in the suspension or revocation of accreditation.

Vi.1.1.1 Chief radiologist responsibilities

The criteria for the MAP require that mammography be performed in a radiological facility under the direct control of a radiologist. The chief radiologist takes full responsibility for all radiological services, including supervision of the QAP, the CQMP and the medical radiation technologists involved with the mammography programme at the facility.

In cases where the chief radiologist is off-site, on-site visitations ought ideally to be carried out on at least a monthly basis. A log of these visits, signed by the chief radiologist, needs to be kept, and may be requested at any time. In remote areas of Canada where such visits may not be feasible, the CAR MAP will have the discretion to judge each case on an individual basis and make accommodations as required.

Vi.1.1.2. Interpreting physician qualifications

The initial requirements for interpreting physicians and locum tenens staff involved in the supervision and interpretation of mammography include:

— Certification in Diagnostic Radiology, ideally by the Royal College of Physicians and Surgeons of Canada and/or the Collège des Médecins du Québec. Also acceptable are equivalent foreign radiologist qualifications if the radiologist is certified by a recognized certifying body and holds a valid provincial licence.
— Forty hours of continuing professional development (CPD) credits documented in breast imaging within the Maintenance of Certification programme of the Royal College of Physicians and Surgeons of Canada. It is required that at least half of these credits be Section 1 (accredited group learning activities) or Section 3 (accredited self-assessment programmes), and the remainder can be properly documented Section 2 type (non-accredited meetings, readings, videotapes, CD-ROM, etc.). Also, 15 hours of the CPD credits ought to ideally have been earned no longer than three years prior to the application for participation in the accreditation programme. A list that includes dates, breast imaging course name and number of hours will be accepted. Time spent in residency specifically devoted to breast imaging will also be accepted, if properly documented by the radiologist.
— Interpret and/or give a second read of (preferably) a minimum of 1000 mammograms per year and maintain records concerning outcome data for correlation of positive mammograms to biopsies performed and the number of cancers detected. The CAR MAP recognizes that this number may be unattainable in certain circumstances, and in these cases a minimum of

480 reads per year will be accepted. Any radiologist reading below 1000 mammograms per year needs to provide the CAR MAP with justification for this on the basis of demographic or geographic challenges. Documentation ought to be available on request.

The requirements for renewal of accreditation for physicians involved in the performance, supervision and interpretation of mammography include:

— Ideally, 15 hours of CPD credits earned in breast imaging within the Maintenance of Certification programme since the last three year accreditation. At least half of these credits must be from Section 1 or Section 3, and the remainder can be properly documented Section 2 credits.
— Continuing to interpret and/or give second read on a (preferred) minimum of 1000 mammograms per year and maintain records concerning outcome data for correlation of positive mammograms to biopsies performed and the number of cancers detected. The CAR MAP recognizes that in certain circumstances this number may be unattainable and in these cases a minimum of 480 reads per year will be accepted. Any radiologist reading below 1000 mammograms per year ought to provide the CAR MAP with justification for this, in the light of demographic or geographic challenges. Documentation needs to be available on request.

VI.1.2. Example: Mexico

In Mexico, qualifications and responsibilities of the radiologist who interprets mammograms are established by the NOM-041 official regulation [143]. Initial qualifications for a breast radiologist are to be a physician with a professional degree and certificate, to have completed the specialty of radiology and imaging in a recognized educational or health institution, and to have achieved board certification in radiology from the Mexican Board of Radiology and Imaging. To become a breast radiologist, a one year high specialty course on breast imaging is required, followed by an 'added qualification in breast images' granted by the same board. Besides the specialization course, other requirements for taking the 'added qualification' exam include professional experience in breast imaging and the interpretation of mammograms, breast ultrasound and interventional breast procedures. According to NOM-041, the radiologist in a mammography service is required to interpret at least 2000 mammograms annually, dedicate a large part of their professional performance to breast imaging diagnosis, be expert in the activities of breast cancer screening and diagnosis, have experience in other breast imaging modalities (ultrasound, magnetic resonance), have the skill and expertise to perform breast biopsies and be part of the multidisciplinary team

of radiologists, pathologists, surgeons and nurses who manage breast cancer. In Mexico in 2020, there were more than 500 board certified radiologists who had additional qualifications to interpret breast images.

The responsibilities of breast radiologists are the interpretation of the mammograms and the follow-up with patients, the monitoring of all aspects of the breast image quality and the radiation protection programme and the continuous education of the technical staff. Also, the radiologist ought to oversee the QC reports of the CQMP and the technical staff and the activity of the technical personnel. Radiologists are responsible for keeping the radiation protection programme and all QC records updated and carrying out internal and external audits to ensure the quality of the service.

VI.1.3. Example: Belgium (Europe)

Belgium, as with many other countries in the European Union, has based the needs for professional training on the European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis [6]. Screening can be centralized, with one organization responsible for imaging, first reading and second reading in a larger region, or it can be decentralized, with imaging and first reading in (independent) mammographic units and, most often, a centralized location for second reading. In the European Guidelines, the needs for first and second readers are different. Images are read by board certified radiologists. In addition, each screening radiologist needs to have had specific training in both diagnostic (symptomatic) mammography and screening mammography, participate in a continuing medical education programme and in any relevant external quality assessment scheme, and undertake to read a minimum of 5000 screening cases per year in centralized programmes. Radiologists carrying out second reading in the non-centralized programmes ought to read a similar number. In addition, each radiologist needs to have access to pathology and surgical follow-up data, attend multidisciplinary review and clinical management meetings, be involved with symptomatic breast work — ideally having skills in clinical examination of the breast — and be fully experienced in all assessment techniques, including the ability to perform ultrasound, FNAC or core biopsy. The European Commission Initiative on Breast Cancer is updating these guidelines.[2] They suggest that mammography readers read between 3500 and 11 000 mammograms annually in organized mammography screening programmes. New guidelines for training will be derived from an ongoing survey and literature study that started in 2019.

In Belgium, specific rules have been added at the transition of SFM to digital mammography. Radiologists with experience in SFM had to train themselves

[2] https://health care-quality.jrc.ec.europa.eu/european-breast-cancer-guidelines

with the digital techniques for eight hours (i.e. four hours of theory and four hours of practice). The knowledge needs to be certified via the successful reading of a test set in the second reading room.

VI.2. MEDICAL RADIATION TECHNOLOGIST

The medical radiation technologist (also known as radiographer or radiologic technologist) is an essential part of the medical team in a mammography service. The medical radiation technologist performs the exam, taking the image after the optimal positioning of the patient's breast on the mammography unit and the application of adequate compression, and performs QC tests, detects and reports problems in the equipment, ensures safety and optimizes dose. The ultimate goal of the medical radiation technologist's tasks is to provide the radiologist with images of the required diagnostic quality to perform an accurate interpretation while ensuring the patient's safety and comfort [6, 108].

The medical radiation technologist needs to have adequate education and specialized training followed by certification or licensing. The IAEA recommends that all personnel in a mammography service, including medical radiation technologists, meet the minimum needs of education and training [2, 5]. The transition from SFM to CRM and DDM requires that the medical radiation technologist review images in a workstation. It will demand specific training on radiology information system and PACS platforms, their software tools and display protocols to help. Medical radiation technologists will need to adjust to the new digital environment [107].

VI.2.1. Example: United States of America

In the United States, the Mammography Quality Standards Act, a national set of regulations for mammography services developed and implemented by the FDA, establishes that medical radiation technologists ought to have a general licence to perform radiological procedures or a board certification after fulfilling an initial training of 40 contact hours in mammography training and performing 25 supervised examinations [144]. Before medical radiation technologists may independently perform mammographic examinations using any mammographic modality in which they were not previously trained (e.g. SFM, CRM or DDM technology), the medical radiation technologists need to have at least eight hours of training in the new modality. In order to continue performing mammograms, there are continuing education and continuum experience needs. The most frequent education degree of mammography medical radiation technologists in the USA prior to the licence or certification was an 'associates degree' — an

undergraduate degree granted after a two- or three-year postsecondary studies programme with a level of qualification between high school diploma and a bachelor's degree [145].

VI.2.2. Example: Belgium (Europe)

In the European Guidelines for Breast Cancer Screening and Diagnosis [6], chapters on skills and training needs for a medical radiation technologist in mammography are included. Training in the various aspects of the radiographic standards related to high quality screening is required. Medical radiation technologists carrying out breast screening mammography ought to attend a recognized training facility and ensure they are participating in CPD. In order to achieve the radiographic standards required for high quality mammographic breast screening, all medical radiation technologists participating in the breast screening programme are expected to undergo a programme of training. This needs to be carried out in a recognized training centre. The training programme ought to consist of two parts: an academic part of three to five days, and a clinical part that depends on the experience and existing skills of the medical radiation technologist, for typically two to six weeks. Especially for the medical radiation technologist, knowledge, skills and competencies for screen-film versus digital mammography are different. The European Breast Cancer Initiative is preparing an update of the training needs.[3]

VI.2.3. Example: Mexico

In Mexico, the NOM-041 official regulation establishes the needs and responsibilities of the medical radiation technologists who work in a breast imaging service [143]. Administrative requirements are a professional certificate recognizing the individual's qualifications as a medical radiation technologist and a technical level diploma in radiology, issued by a recognized medical institution. Additionally, proof of specific training in mammography or a tutorial or demonstration course (theoretical and practical) ought to be provided. To be recognized as proficient in breast imaging techniques, the medical radiation technologist is required to have performed at least 150 mammograms that have been judged to be of high quality by an experienced breast medical radiation technologist.

The medical radiation technologist in a breast imaging service is responsible for obtaining images of clinical quality with as low exposure as is reasonably achievable, having the ability to obtain good quality images (at least 97%, with

[3] Ibid.

adequate quality for interpretation, less than 3% that are technically inadequate), having the capacity to take the necessary additional projections when required and being knowledgeable about the equipment and materials used in the service. The breast medical radiation technologist is responsible for carrying out image QC activities and understanding the proper use of the AEC. A medical radiation technologist who works in a diagnostic service needs to be familiar with the use of the mammography system to perform interventions. Ideally, they ought to be able to use stereotactic (location) equipment and other procedures in performing biopsies and be familiar with other breast imaging techniques (MRI, ultrasound, etc.). They need to be able to create an environment of trust and respect, informing the patient about the study technique clearly and effectively.

VI.2.4. Example: United Kingdom

In the United Kingdom, medical radiation technologists (known as radiographers) need to complete an approved three to four-year course on diagnostic radiology which includes practice with patients. A postgraduate certification in mammography is offered. The National Health Service Breast Screening programme is a four tier structure where different roles and responsibilities are defined for radiographers at four levels of mammographic practice, from assistant up to consultant practitioner. Each level defines the required education and training.

Registered medical radiation technologists wanting to specialize in mammography need to successfully complete a postgraduate course in mammography. Courses are run by national training centres in collaboration with universities. All courses are accredited and validated by an external body. In-house training is not acceptable as an alternative to an accredited or approved course. Training will ensure that medical radiation technologists are technically expert and well informed to respond to the individual needs of the patient and ensure quality service delivery.

Medical radiation technologists ought to be able to establish an effective communication process in order to explain the mammographic procedure, what is expected and how it will proceed, as it has been shown that patients will tolerate compression better if they understand its need and its importance and can indicate if the pressure becomes too uncomfortable.

VI.3. CLINICALLY QUALIFIED MEDICAL PHYSICIST

CQMPs assure the quality standards of a mammography service. Their main tasks are to provide advice on facility design and equipment selection

(including the PACS), perform acceptance, commissioning and routine quality tests of the mammography unit, assess image quality, measure radiation dose, perform radiation protection tasks, set diagnostic reference levels, optimize the use of radiation and provide guidance and advice to the medical radiation technologists who carry out their part of the QC tests.

A CQMP who is specialized in diagnostic and interventional radiology medical physics has usually completed a postgraduate academic programme complemented by additional high level competencies to understand the technical complexities of medical imaging [146]. A CQMP needs to be within a medical facility to practice unsupervised. They ideally have experience in a wide range of situations and are capable of making expert decisions on the basis of sound scientific evidence and experience. In order to gain this ability, the new graduate needs to be supervised by one or more competent senior CQMPs and follow a structured clinical training programme [147].

The IAEA recently established guidelines for the certification of CQMPs, which are endorsed by the International Medical Physics Certification Board and the International Organization for Medical Physics [148]. CQMPs are defined as physicists working in health care who have received adequate academic postgraduate education in medical physics and relevant supervised clinical training. They may work as members of multidisciplinary teams that provide services to patients in radiotherapy, nuclear medicine, diagnostic and interventional radiology. They may also work in other areas where ionizing or non-ionizing radiation or physics principles are used for the diagnosis and treatment of patients. According to the IAEA guidelines, minimum requirements for CQMP certification consist of four components [149]:

— A university degree in physics, engineering or equivalent physical science with sufficient knowledge in mathematics and a broad understanding of experimental and theoretical physics;
— A postgraduate medical physics academic education;
— A research component is desirable though significant research expertise is not usually a prerequisite in clinical practice;
— Documentation of activities (portfolio or logbook) for a certain number of years of clinical training in a supervised and structured residency programme.

The postgraduate university degree and clinical training programme need to be accredited by an appropriate body so as to prove adherence to quality standards (for example through internal or external audits). The scope, content and assessment tools used in the education and clinical training programme need to be documented for accreditation or audit purposes. To date, medical physics programmes accreditation is provided by national designated entities

(e.g. Commission on Accreditation of Medical Physics Education Programs in the USA and the Australasian College of Physical Scientists and Engineers in Medicine for academic education in Australia and New Zealand). The International Organization for Medical Physics has also established the International Organization for Medical Physics Accreditation Board, which accredits medical physics programmes and training institutions and centres as well as education and training events at an international level [148].

VI.3.1. Example: United States of America

The Mammography Quality Standards Act in the USA dictates the guidelines to assure that all women have access to quality mammography for the early detection of breast cancer. The Mammography Quality Standards Act is a national set of regulations aimed at mammography services, developed and implemented by the FDA [144]. CQMPs (that is, those who can perform clinical professional work independently) ought to ideally meet the following criteria: (1) They need to have a licence or approval by a State to perform mammography surveys, or be certified by a board in medical physics or diagnostic medical physics; and (2) they ought to have a Masters' or higher degree in a physical science, at least 20 hours of mammography facility survey training and have the experience of conducting surveys of at least one mammography service and at least ten mammography units. Before CQMPs may perform evaluations on a mammography modality different to the one in which they were initially trained, they need to have at least eight hours of training in the new modality [144].

VI.3.2. Example: Europe

On 5 December 2013, the European Council promulgated Directive 2013/59/EURATOM "laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation" [128, 149], that emphasizes the need for justification of medical exposure (including for asymptomatic individuals), introduces requirements concerning patient information and strengthens those for recording and reporting doses from radiological procedures, the use of diagnostic reference levels, the availability of dose indicating devices and the improved role and support of the medical physics experts in imaging [150]. According to the 2013/59/EURATOM, medical physics expert is defined as an individual or, if provided for in national legislation, a group of individuals — having the knowledge, training and experience to act or give advice on matters relating to radiation physics applied to medical exposure, whose competence in this respect is recognized by the competent authority [128]. The commentary regarding the role and competencies of a medical physics expert

was published in the European Commission Radiation Protection Report No 174 'European Guidelines on the Medical Physics Expert' [151], and the mission statement for medical physicists and medical physics experts was as stated as follows: Medical Physicists and

> "Medical Physics Experts will contribute to maintaining and improving the quality, safety and cost-effectiveness of health care services through patient-oriented activities requiring expert action, involvement or advice regarding the specification, selection, acceptance testing, commissioning, quality assurance/control and optimised clinical use of medical radiological devices and regarding patient risks from ionising radiations including protection from such radiations, installation design and surveillance, and the prevention of unintended or accidental exposures; all activities will be based on current best evidence or own scientific research when the available evidence is not sufficient" [151].

In terms of education and professional training, the European Qualifications Framework (EQF) for lifelong learning introduced by the European Parliament and Council was adopted. According to the EQF, the knowledge, skills and competencies for recognition of medical physicist and medical physics expert status are to be gained initially through learning in an institution of higher education (EQF Level 6) and structured clinical training in a residency within an accredited health care institution to gain recognition as a CQMP (EQF Level 7+). This can subsequently be developed to expert level (EQF Level 8, the highest level of the EQF) through further structured advanced experience and CPD in order to gain recognition as a medical physics expert by competent authorities (or the equivalent expert level in the fields of medical devices and physical agents other than radiological devices and ionizing radiation). The qualification framework would make it possible for more individuals to achieve CQMP and medical physics expert status through its flexibility, cost effectiveness and lifelong learning approach. It also facilitates the mobility of the CQMP and medical physics expert in Europe through an agreed set of minimum criteria to achieve such a status [152].

VI.3.3. Example: United Kingdom

In the United Kingdom, the National Health Service Cancer Screening Programme establishes that all CQMPs providing mammography medical physics services ought to have received basic training in general diagnostic radiological physics and radiation protection, need to have received basic training in mammography physics and update courses and ought to have undertaken

practical training in medical physics departments with recognized expertise in mammography physics. In order to maintain awareness of technology and experience they, ideally, need to perform QA surveys on at least six mammography units at least once a year, or equivalent.

The training of a CQMP in mammography physics includes the basic elements of a training in diagnostic imaging physics (e.g. imaging systems, film processing and darkroom, CR and DR imaging, AEC devices, ionizing radiation dosimetry and principles of measurement, radiation protection, assessment of image quality through objective tests and assessment of image quality with phantoms) as well as specific aspects related to mammography. In order to perform the SFM equipment tests, the CQMP ought to be trained in the operation of equipment, inspection of screen-film systems, processing and all related criteria, inspection of viewing conditions, reject analysis, assessment of collimation, AEC performance, assessment of radiographic parameters, assessment of image receptor (for uniformity and artefacts) and assessment of image quality. For digital systems (CRM and DDM), the training needs to include the operation of equipment, relevant tests from SFM systems (above) and modified tests from SFM [147]. More on the responsibilities of CQMPs in the QA of medical imaging can also be found in Chapter 19 of the IAEA Diagnostic Radiology Physics handbook [28].

VI.3.4. Example: Mexico

In Mexico, official regulation NOM-041 establishes the needs and responsibilities for a CQMP in a mammography breast imaging service [143]. The needs are a university degree and professional certificate of physicist or engineer and, preferably, a Master of Science with specialty in medical physics. In terms of training, the person needs to document at least 40 hours of supervised training in QA and QC tasks corresponding to each modality of mammography techniques (e.g. film based and digital).

The responsibilities of the CQMP are to conduct evaluation of the mammography X ray systems to assess image quality, to determine the dose received by patients and to monitor whether changes have occurred that could decrease the diagnostic capacity of the equipment or increase the radiation dose to the patient or personnel. The CQMP needs to perform a number of annual equipment QC tests (listed in the NOM-041, Ref. [143]), and to review the reports made by technical personnel in mammography with the frequency indicated in the NOM-041 documents, and issue pertinent recommendations for remediation, if necessary.

VI.4. SERVICE ENGINEERS, VENDORS

Mammography is a complex system involving multiple components that interact with one another. It is, therefore, essential that those individuals responsible for servicing mammography equipment be knowledgeable in all aspects of this process. Training of service personnel is generally the responsibility of their employer. Larger companies that are also equipment manufacturers typically operate their own training programmes, while smaller companies, which may be exclusively in the business of providing service, may use third party training programmes for this purpose. It is not acceptable for a vendor simply to install a system on-site and not follow through with proper set-up, calibration and on-site user training.

All imaging systems are composed of four main elements: (1) the X ray system, consisting of the power supply, control and X ray tube, the AEC and the gantry on which components are mounted that provides the mechanical motions for breast positioning; (2) the X ray detection system; (3) the processing system; and (4) the display and software. While the first component is constant across all mammography systems, it is primarily the other three that differentiate the available technologies. In particular, the set-up for the AEC is dependent on the image receptor and will be different among SFM, CRM and DDM technology.

It is not uncommon, especially in CRM systems, for the X ray source and gantry to come from different manufacturers than the detector system and processor. Often the mammography unit (Element 1) is in place before the hospital decides to adopt a digital technology. If the CRM system (Elements 2 and 3, ideally from the same manufacturer) is purchased according to the lowest price, there may not have been adequate consideration about the engineering required to couple the X ray and the image aspects of the system. This often happens in LMIC where resources are limited. In the worst case scenario, the CRM service team installs the CR plates reader, provides the associated plates and cassettes and performs the commissioning tests according to their manual. Generally, the sensitivity index is adjusted on the basis of the measurement of the entrance surface air kerma associated with a standard mammographic technique. The implicit assumption behind this procedure is that the AEC has been independently optimized by the mammography unit service team and that the radiological techniques correctly compensate for breast thickness. If no QAP is in place at the clinical service, most probably the relevant coordination between the two sides will not happen, and the integrated system will fail to comply with the image quality needs. As an example, in Mexico, where a performance evaluation of CRM systems detected severe failures in image quality, it was determined that additional training of service engineers in the specific needs of the CRM technique would be valuable in solving these problems [128, 152].

Appendix VII

EVALUATION OF MAMMOGRAPHY SERVICE

A well organized mammography service requires a comprehensive quality programme with the goal of producing high quality images for the accurate diagnosis and timely treatment of disease. It requires qualified and sufficiently trained personnel with adequate opportunities for continuing education and it needs to be integrated into well structured health systems that provide follow-up care and access to treatment [7, 95]. According to the position paper that the WHO issued in 2014 [95], various conditions need to be applied to achieve a quality mammography service. These conditions include a sufficient health system and financial resources to sustain the service, acquisition and proper maintenance of a mammography system, required supplies, qualified health personnel, QAP, administrative structure for the evaluation of complete mammography service, validated protocols for all steps in the mammography process, performing mammography and confirming its quality, appropriate positioning and acceptable radiation exposure, among other factors [95]. The quality mammography service needs to be monitored and evaluated at certain intervals using process and outcome indicators [7].

Some countries establish evaluation programmes in radiology including mammography. In some countries, these programmes have been made mandatory for mammography (e.g. USA) while some countries conceive it as a voluntary programme (e.g. countries in Europe). The following section shows a few examples of such programmes implemented in different countries and subregions (i.e. USA, Canada, Europe, United Kingdom, Australia and New Zealand).

VII.1. EXAMPLE: UNITED STATES OF AMERICA

The ACR MAP was introduced by the ACR Task Force on Breast Cancer in 1987. The programme is directed by radiologists and medical physicists in the Mammography Accreditation programme of the ACR Commission on Quality and Safety. It offers radiologists an opportunity to review and evaluate their mammography facility, personnel qualifications, image quality, equipment, QA and QC procedures through a constructive peer review mechanism. The accreditation programme was initially conceived as a voluntary programme, but later on became mandatory when the Mammography Quality Standards Act (MQSA) of 1992 required all mammography facilities in the USA to become accredited and certified by 1 October 1994. Currently, the ACR is the largest of

four accrediting bodies approved by the FDA. Under this Act, a facility needs to have a current and valid MQSA certificate (or 'interim notice') to legally perform mammography. Any facility performing mammography without this certificate is subject to sanctions under MQSA. A new facility needs to apply for accreditation of all mammography units and receive a provisional MQSA certificate from the FDA (or US state certifying body) before performing mammography. Further details regarding ACR MAP can be obtained at the ACR's official web site.[4]

VII.2. EXAMPLE: CANADA

The CAR MAP is an initiative instituted over 20 years ago to ensure that the quality of mammography images meets high standards. This voluntary programme offers radiologists the opportunity for peer review and evaluation of their facility's staff qualifications, equipment performance, QC and QAP, image quality, dose and processor QC. Facilities seeking accreditation by the CAR MAP are assessed for compliance in these four quality areas of the programme:

— Personnel requirements: The right people conduct a quality examination and oversee the rendering of optimal diagnostic images;
— Quality control: The appropriate tests are completed through the implementation of a QAP and monitored QC to ensure the acquisition and presentation of optimal quality medical images;
— Equipment specifications: The right equipment operates in the manner in which it was intended;
— Breast image quality: A systematic image assessment by a qualified reviewer, ensuring the facility regularly evaluates the quality of its diagnostic images and the associated radiation doses.

These quality areas are assessed at specified regular intervals through the different stages of the accreditation process: the application, image evaluation as well as the maintenance of accreditation status. Facilities successfully completing all the CAR requirements will be granted accreditation for a 3 year period and will be listed on the CAR web site. Further details regarding the CAR MAP are found on the CAR official web site.[5]

---

[4] https://www.acraccreditation.org/modalities/mammography
[5] https://car.ca/patient-care/map

VII.3. EXAMPLE: EUROPE

EUREF is a pan-European organization operated on a non-profit basis to promote high quality mammography care in Europe. The roles of EUREF include the development and dissemination of the European guidelines, certification of breast services and mammography equipment, training and providing support and advice upon request. One of the key activities of EUREF is certification of breast screening and diagnostic services in Europe on a voluntary basis. The certification is at the European level and in compliance with the international regulation on certification of the International Organization for Standardization. The certification allows for tangible and demonstrable recognition of adherence to a recognized quality system and achievement of satisfactory outcomes. It takes into account the special requirements of both symptomatic and screening services.

Further details regarding the certification protocols can be found on the EUREF web site.[6]

VII.4. EXAMPLE: UNITED KINGDOM

In the United Kingdom, a number of accreditation systems are in place for different professionals involved in the breast screening process. These include the accreditation of readers, pathologists and laboratories. The Royal College of Radiologists is responsible for professional standards and training in radiology, while standards for mammographers (radiographers) are specified by the Society of Radiographers and the College of Radiographers. In addition, medical physics and clinical engineering accreditation is overseen by the United Kingdom Accreditation Service, a national accreditation body appointed by the government to assess organizations that provide certification, testing, inspection and calibration services. The Department of Health Advisory Committee on Breast Cancer Screening is responsible for considering issues relating to breast cancer screening and for making recommendations on policies for screening practice in England.

The Quality Standard for Imaging (formally known as Imaging Services Accreditation Scheme) has been developed by the Royal College of Radiologists, the Society of Radiographers and the College of Radiographers to set out the criteria that define a quality imaging service. Accreditation by the United Kingdom Accreditation Service for imaging services is a patient focused assessment that is designed to give stakeholders, service users, patients and their carers confidence in their diagnosis and all aspects of their care. The Quality Standard for Imaging

[6] https://www.euref.org/certification

provides a framework[7] for the NHS and private sectors to offer consistently high quality services delivered by competent staff working in safe environments. The United Kingdom Accreditation Service assesses imaging services through regular monitoring to ensure that the standard's requirements are maintained. Accreditation to standards is supported by NHS England, NHS Northern Ireland and NHS Wales and is recognized by the Care Quality Commission.

VII.5. EXAMPLE: AUSTRALIA AND NEW ZEALAND

In Australia, the Medical Imaging Accreditation Programme is jointly administered by the Royal Australian and New Zealand College of Radiologists and the National Association of Testing Authorities. It accredits medical imaging services against the Standards of Practice for Diagnostic and Interventional Radiology. The Medical Imaging Accreditation Programme is designed by the profession for the profession and uses professional peer review and assessment to facilitate accreditation. This is a voluntary programme; however, it is recognized under the Diagnostic Imaging Accreditation Scheme. The Australia Health Insurance Act of 1973 was amended in 2007 to establish a Diagnostic Imaging Accreditation Scheme linking mandatory accreditation to the payment of Medicare benefits for clinical radiology and non-radiology services.

International Accreditation New Zealand is the accrediting body for clinical radiology services in New Zealand. Their accreditation is a formal recognition of a clinical radiology service's skills, expertise, competence, management systems, procedures and facilities on the basis of independent assessment by peer experts.

The Mammography Quality Assurance Program is implemented in both Australia and New Zealand to provide QA assessment for mammography sites. Diagnostic mammography services in those countries are required to participate in this programme every three years to meet the Standards of Practice for Diagnostic and Interventional Radiology. The programme is open to private medical imaging practices and medical imaging departments of public and private hospitals and has been declared under Commonwealth Qualified Privilege. Participation is machine-specific; sites operating more than one mammography machine need to apply to have each machine assessed.

---

[7] https://www.rcr.ac.uk/clinical-radiology/service-delivery/quality-standard-imaging-qsi

REFERENCES

[1] SUNG, H., et al., Global Cancer Statistics 2020: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. CA Cancer J. Clin. **71(3)** (2021) 209–249.

[2] INTERNATIONAL ATOMIC ENERGY AGENCY, Quality Assurance Programme For Digital Mammography, IAEA Human Health Series No. 17, IAEA, Vienna (2011).

[3] LAUBY-SECRETAN, B., et al., Breast-cancer screening—viewpoint of the IARC Working Group, N. Engl. J. Med. **372** (2015) 2353–2358.

[4] FERLAY J, et al., Global Cancer Observatory: Cancer Today. International Agency for Research on Cancer, Available from: https://gco.iarc.fr/today (2020).

[5] INTERNATIONAL ATOMIC ENERGY AGENCY, Quality Assurance Programme for Screen Film Mammography, IAEA Human Health Series No. 2, IAEA, Vienna (2009).

[6] EUROPEAN REFERENCE ORGANIZATION FOR QUALITY ASSURED BREAST SCREENING AND DIAGNOSTIC SERVICES, European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis, 4th edn, EC, Luxembourg (2006).

[7] PAN AMERICAN HEALTH ORGANIZATION, Mammography Services Quality Assurance: Baseline Standards for Latin America and the Caribbean, PAHO, Washington, DC (2016).

[8] INTERNATIONAL ATOMIC ENERGY AGENCY, Worldwide Implementation of Digital Imaging in Radiology, IAEA Human Health Series No. 28, IAEA, Vienna (2015).

[9] INTERNATIONAL ELECTROTECHNICAL COMMISSION, Medical electrical equipment — Part 2-45: Particular requirements for the basic safety and essential performance of mammographic X ray equipment and mammographic stereotactic devices. IEC 60601-2-45:2011, IEC, Geneva (2015).

[10] NORWECK, J.T., et al., ACR-AAPM-SIIM technical standard for electronic practice of medical imaging, J. Dig. Imag. **26** (2013) 38–52.

[11] AMERICAN COLLEGE OF RADIOLOGY, ACR Practice Parameter for the Performance of Screening and Diagnostic Mammography, ACR, Reston, VA (2018).

[12] MARSHALL, N.W., VAN ONGEVAL, C., BOSMANS, H., Performance evaluation of a retrofit digital detector-based mammography system, Phys. Med. **32** (2016) 312–322.

[13] INTERNATIONAL ATOMIC ENERGY AGENCY, Radiation Protection and Safety in Medical Uses of Ionizing Radiation, IAEA Safety Standards Series No. SSG-46, IAEA, Vienna (2018).

[14] NATIONAL COUNCIL ON RADIATION PROTECTION AND MEASUREMENTS, Structural Shielding Design for Medical X ray Imaging Facilities, NCRP Report No. 147, NCRP, Bethesda, MD (2004).

[15] SUTTON, D.G., MARTIN, C.J., WILLIAMS, J.R., PEET, D.J., Radiation Shielding for Diagnostic Radiology, 2nd edn, British Institute of Radiology, London, (2012).

[16] MALONE, J., O'REILLY, G., O'CONNOR, U., GALLAGHER, A., SHEAHAN, N., The Design of Diagnostic Medical Facilities Where Ionising Radiation Is Used, Radiological Protection Institute of Ireland, Dublin (2009).

[17] DEUTSCHES INSTITUT FÜR NORMUNG, Medizinische Röntgenanlagen bis 300 kV: Regeln für die Auslegung des baulichen Strahlenschutzes, DIN 6812:2013-06, DIN Berlin (2013).
[18] HEALTH CANADA, Radiation Protection and Quality Standards in Mammography: Safety Procedures for the Installation, Use and Control of Mammographic X ray Equipment. Safety Code 36, Health Canada (2013).
[19] EUROPEAN FEDERATION OF ORGANISATIONS FOR MEDICAL PHYSICS, Mammo Protocol, EFOMP, Utrecht (2015).
[20] EUROPEAN COMMISSION, DIRECTORATE-GENERAL FOR HEALTH AND CONSUMERS, KARSA, L., HOLLAND, R., BROEDERS, M., et al. (Eds), European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis: fourth edition, supplements, Publications Office, (2013), https://data.europa.eu/doi/10.2772/13196
[21] AMERICAN COLLEGE OF RADIOLOGY, ACR 2018 Digital Mammography Quality Control Manual, ACR, Reston, VA (2018).
[22] MAHESH, M., AAPM/RSNA physics tutorial for residents: Digital mammography: An overview, Radiographics **24** 6 (2004) 1747–1760.
[23] BLUME, H.R., HO, A.M.K., STEVENS, F., STEVEN, P.M., Practical aspects of grayscale calibration of display systems, Proc. SPIE **4323** (2001) 28–41.
[24] NATIONAL ELECTRICAL MANUFACTURERS ASSOCIATION, "Part 14: Grayscale standard display function", Digital Imaging and Communications in Medicine (DICOM), NEMA, Rosslyn, USA (2011).
[25] SAMEI, E., et al., Assessment of display performance for medical imaging systems: Executive summary of AAPM TG18 report, Med. Phys. **32** 4 (2005) 1205–1225.
[26] BOSMANS, H., et al., Technical and clinical breast cancer screening performance indicators for computed radiography versus direct digital radiography, Eur. Radiol. **23** 10 (2013) 2891–2898.
[27] YOUNG, K.C, ODUKO, J.M., Evaluation of Kodak DirectView mammography computerised radiography system, National Coordinating Centre for the Physics of Mammography, NHSBSP Equipment Report 0504 (2005).
[28] INTERNATIONAL ATOMIC ENERGY AGENCY, Diagnostic Radiology Physics: A Handbook for Teachers and Students, Non-serial Publications, IAEA, Vienna (2014).
[29] SEIBERT, J.A., BOONE, J.M., COOPER V.N., III, LINDFORS, K.K., Cassette-based digital mammography, Technol. Cancer Res. Treat. **3** 5 (2004) 413–427.
[30] AMERICAN ASSOCIATION OF PHYSICISTS IN MEDICINE, Equipment requirements for quality control for mammography, AAPM Report No. 29, AAPM, College Park, MD (1990).
[31] AMERICAN COLLEGE OF RADIOLOGY, ACR 1999 Mammography Quality Control Manual, ACR, Reston, VA (1999).
[32] BUSHBERG, J.T., SIEBERT, J.A., LEIDHOLDT, E.M., BOONE, J.M., The Essential Physics of Medical Imaging, Lippincott Williams & Wilkins, Philadelphia (2011).
[33] LEGOOD, R., GRAY, A., A cost comparison of full field digital mammography (FFDM) with film-screen mammography in breast cancer screening, NHSBSP Equipment Report **0403** (2004).

[34] HOWELL, A., The emerging breast cancer epidemic: Early diagnosis and treatment, Breast Cancer Res. **12** Suppl. 4 (2010) S10.
[35] EUROPEAN SOCIETY OF RADIOLOGY, Renewal of radiological equipment, Insights Imag. **5** (2014) 543–546.
[36] UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, Health Insurance Portability and Accountability Act of 1996 (HIPAA), Washington, DC (1996).
[37] BROWN, H., et al., Determining the most clinically and cost-effective way of implementing digital mammography services for breast screening in NHS Scotland, Health Technology Assessment [HTA] Report No. 10, NHS Quality Improvement Scotland (2008).
[38] PRUMMEL, M.V., et al., Digital compared with screen-film mammography: Measures of diagnostic accuracy among women screened in the Ontario breast screening program, Radiology **278** 2 (2016) 365–373.
[39] NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE, Artificial intelligence in mammography, Medtech innovation briefing [MIB242], NICE (2021).
[40] BATCHU, S., LIU, F., AMIREH, A., WALLER, J., UMAIR, M., A review of applications of machine learning in mammography and future challenges, Oncology **99** (2021) 483–490.
[41] DEMBROWER, K., et al., Comparison of a deep learning risk score and standard mammographic density score for breast cancer risk prediction, Radiol. **294** 2 (2020) 265–272.
[42] YALA, A., LEHMAN, C., SCHUSTER, T., PORTNOI, T., BARZILAY, R., A deep learning mammography-based model for improved breast cancer risk prediction, Radiol. **292** 1 (2019) 60–66.
[43] SECHOPOULOS, I., TEUWEN, J., MANN, R., Artificial intelligence for breast cancer detection in mammography and digital breast tomosynthesis: State of the art, Semin. Cancer Biol. **72** (2021) 214–225.
[44] EUROPEAN SOCIETY OF RADIOLOGY, What the radiologist should know about artificial intelligence — an ESR white paper, Insights Imag. **10** (2019) 44.
[45] PISANO, E.D., et al., Diagnostic accuracy of digital versus film mammography: Exploratory analysis of selected population subgroups in DMIST, Radiol. **246** 2 (2008) 376–383.
[46] HOFVIND, S., et al., Mammographic performance in a population-based screening program: Before, during, and after the transition from screen-film to full-field digital mammography, Radiol. **272** 1 (2014) 52–62.
[47] GLYNN, C.G., et al., Effect of transition to digital mammography on clinical outcomes, Radiol. **260** 3 (2011) 664–670.
[48] VAN BOMMEL, R.M. G., et al., Interval breast cancer characteristics before, during and after the transition from screen-film to full-field digital screening mammography, BMC Cancer **17** (2017) Article 315.
[49] WEBER, R.J.P., et al., Characteristics and prognosis of interval cancers after biennial screen-film or full-field digital screening mammography, Breast Cancer Res. Treat. **158** 3 (2016) 471–483.

[50] CAMPARI, C., et al., Impact of the introduction of digital mammography in an organized screening program on the recall and detection rate, J. Dig. Imag. **29** 2 (2016) 235–242.
[51] PERRY, N.M., et al., The impact of digital mammography on screening a young cohort of women for breast cancer in an urban specialist breast unit, Eur. Radiol. **21** 4 (2011) 676–682.
[52] FEELEY, L., et al., Digital mammography in a screening programme and its implications for pathology: A comparative study, J. Clin. Pathol. **64** 3 (2011) 215–219.
[53] KNOX, M., et al., Impact of full field digital mammography on the classification and mammographic characteristics of interval breast cancers, Eur. J. Radiol. **84** 6 (2015) 1056–1061.
[54] NEAL, C.H., COLETTI, M.C., JOE, A., JEFFRIES, D.O., HELVIE, M.A., Does digital mammography increase detection of high-risk breast lesions presenting as calcifications?, AJR Am. J. Roentgenol. **201** (2013) 1148–1154.
[55] SERADOUR, B., HEID, P., ESTEVE, J., Comparison of direct digital mammography, computed radiography, and film-screen in the French national breast cancer screening program, AJR Am. J. Roentgenol. **202** (2014) 229–236.
[56] TIMMERMANS, L., et al., Impact of the digitalisation of mammography on performance parameters and breast dose in the Flemish Breast Cancer Screening Programme, Eur. Radiol. **24** 8 (2014) 1808–1819.
[57] VINNICOMBE, S., et al., Full-field digital versus screen-film mammography: comparison within the UK breast screening program and systematic review of published data, Radiol. **251** (2009) 347–358.
[58] GREENWALD, Z.R., et al., Mobile screening units for the early detection of cancer: A systematic review, Cancer Epidemiol. Biomarkers Prev. **26** 12 (2017) 1679–1694.
[59] BLUEKENS, A.M., HOLLAND, R., KARSSEMEIJER, N., BROEDERS, M.J., DEN HEETEN, G.J., Comparison of digital screening mammography and screen-film mammography in the early detection of clinically relevant cancers: A multicenter study, Radiol. **265** (2012) 707–714.
[60] DE MUNCK, L., et al., Digital vs screen-film mammography in population-based breast cancer screening: Performance indicators and tumour characteristics of screen-detected and interval cancers, Br. J. Cancer **115** 5 (2016) 517–524.
[61] DEL TURCO, M.R., et al., Full-field digital versus screen-film mammography: Comparative accuracy in concurrent screening cohorts, AJR Am. J. Roentgenol. **189** 4 (2007) 860–866.
[62] LEWIN, J.M., et al., Comparison of full-field digital mammography with screen-film mammography for cancer detection: Results of 4,945 paired examinations, Radiol. **218** 3 (2001) 873–880.
[63] PISANO, E.D., et al., Diagnostic performance of digital versus film mammography for breast-cancer screening, N. Engl. J. Med. **353** 17 (2005) 1773–1783.
[64] SKAANE, P., HOFVIND, S., SKJENNALD, A., Randomized trial of screen-film versus full-field digital mammography with soft-copy reading in population-based screening program: Follow-up and final results of Oslo II study, Radiol. **244** (2007) 708–717.

[65] FRAZER, H.M., QIN, A.K., PAN, H., BROTCHIE, P., Evaluation of deep learning-based artificial intelligence techniques for breast cancer detection on mammograms: Results from a retrospective study using a BreastScreen Victoria dataset, J. Med. Imag. Radiat. Oncol. **65** (2021) 529–537.
[66] CARTER, S.M., et al., The ethical, legal and social implications of using artificial intelligence systems in breast cancer care, Breast **49** (2020) 25–32.
[67] HOSNY, A., PARMAR, C., QUACKENBUSH, J., SCHWARTZ, L.H., AERTS, H.J. W.L., Artificial intelligence in radiology, Nat. Rev. Cancer **18** (2018) 500–510.
[68] WORLD HEALTH ORGANIZATION, Fact Sheets: Breast Cancer, WHO, Geneva (2021). Available at: https://www.who.int/news-room/fact-sheets/detail/breast-cancer. Accessed on 29 Jan. 2023.
[69] WORLD HEALTH ORGANIZATION, Preventing chronic diseases: A vital investment, WHO Global report, WHO, Geneva (2010).
[70] PARKIN, D.M., FERNÁNDEZ, L.M., Use of statistics to assess the global burden of breast cancer, Breast J. **12** Suppl. 1 (2006) S70–80.
[71] SHAH, S.C., KAYAMBA, V., PEEK, R.M., JR., HEIMBURGER, D., Cancer control in low- and middle-income countries: Is it time to consider screening? J. Glob. Oncol. **5** (2019) 1–8.
[72] TFAYLI, A., TEMRAZ, S., ABOU MRAD, R., SHAMSEDDINE, A., Breast cancer in low- and middle-income countries: An emerging and challenging epidemic, J. Oncol. **2010** (2010) 490631.
[73] SANTUCCI, C., et al., Progress in cancer mortality, incidence, and survival: A global overview, Eur. J. Cancer Prev. **29** 5 (2020) 367–381.
[74] MALLATH, M.K., et al., The growing burden of cancer in India: Epidemiology and social context, Lancet Oncol. **15** 6 (2014) e205–212.
[75] ALLEMANI, C., et al., Global surveillance of trends in cancer survival 2000–14 (CONCORD-3): Analysis of individual records for 37 513 025 patients diagnosed with one of 18 cancers from 322 population-based registries in 71 countries, Lancet **391** 10125 (2018) 1023–1075.
[76] INTERNATIONAL AGENCY FOR RESEARCH ON CANCER WORKING GROUP ON THE EVALUATION OF CANCER-PREVENTIVE INTERVENTIONS, Breast Cancer Screening, IARC, Lyon, (2016).
[77] REYNOSO-NOVERÓN, N., et al., Clinical and epidemiological profile of breast cancer in Mexico: Results of the Seguro Popular, J. Glob. Oncol. **3** 6 (2017) 757–764.
[78] ANDERSON, B.O., et al., Early detection of breast cancer in countries with limited resources, Breast J. **9** Suppl. 2 (2003) S51–S59.
[79] JEDY-AGBA, E., MCCORMACK, V., ADEBAMOWO, C., DOS-SANTOS-SILVA, I., Stage at diagnosis of breast cancer in sub-Saharan Africa: A systematic review and meta-analysis, Lancet Glob. Health **4** (2016) e923–e935.
[80] KIM, Y., YOO, K.Y., GOODMAN, M.T., Differences in incidence, mortality and survival of breast cancer by regions and countries in Asia and contributing factors, Asian Pac. J. Cancer Prev. **16** (2015) 2857–2870.

[81] DAVIDSON, A., et al., Stage, treatment and outcomes for patients with breast cancer in British Columbia in 2002: A population-based cohort study, CMAJ Open **1** 4 (2013) E134–141.
[82] BROEDERS, M., et al., The impact of mammographic screening on breast cancer mortality in Europe: A review of observational studies, J. Med. Screen. **19** Suppl. 1 (2012) 14–25.
[83] COLDMAN, A., et al., Pan-Canadian study of mammography screening and mortality from breast cancer, J. Natl Cancer Inst. **106** 11 (2014) dju261.
[84] DONZELLI, A., The benefits and harms of breast cancer screening, Lancet **381** (2013) 799–800.
[85] SEELY, J.M., ALHASSAN, T., Screening for breast cancer in 2018—What should we be doing today? Curr. Oncol. **25** (2018) S115–S124.
[86] TABÁR, L., et al., The incidence of fatal breast cancer measures the increased effectiveness of therapy in women participating in mammography screening, Cancer **125** 4 (2019) 515–523.
[87] AHN, S., et al., Impact of screening mammography on treatment in women diagnosed with breast cancer, Ann. Surg. Oncol. **25** 10 (2018) 2979–2986.
[88] BARTH, R.J., JR., et al., Detection of breast cancer on screening mammography allows patients to be treated with less-toxic therapy, AJR Am. J. Roentgenol. **184** 1 (2005) 324–329.
[89] FREEDMAN, G.M., et al., Routine mammography is associated with earlier stage disease and greater eligibility for breast conservation in breast carcinoma patients age 40 years and older, Cancer **98** 5 (2003) 918–925.
[90] LEUNG, J.W., Screening mammography reduces morbidity of breast cancer treatment, AJR Am. J. Roentgenol. **184** 5 (2005) 1508–1509.
[91] SPARANO, J.A., et al., Adjuvant chemotherapy guided by a 21-gene expression assay in breast cancer, N. Engl. J. Med. **379** 2 (2018) 111–121.
[92] CLINICAL PRINCIPAL COMMITTEE STANDING COMMITTEE ON SCREENING, Population-based Screening Framework. Australian Department of Health, Canberra (2018). Available at: https://www.health.gov.au/resources/publications/population-based-screening-framework
[93] BURHENNE, L.J.W., "Breast cancer screening: General guidelines, program design, and organization", Radiological Diagnosis of Breast Diseases (Friedrich, M., Sickles, E.A., Eds), Springer, Berlin (2000) 347–365.
[94] WORLD HEALTH ORGANIZATION, Cancer control: Early detection. WHO guide for effective programmes, WHO, Geneva (2007).
[95] WORLD HEALTH ORGANIZATION, WHO Position Paper on Mammography Screening, WHO, Geneva (2014).
[96] YAFFE, M.J., et al., Comparative performance of modern digital mammography systems in a large breast screening program, Med. Phys. **40** 12 (2013) 121915.
[97] ROWLANDS, J.A., The physics of computed radiography, Phys. Med. Biol. **47** 23 (2002) 123–166.

[98] BAHL, M., MERCALDO, S., VIJAPURA, C.A., MCCARTHY, A.M., LEHMAN, C.D., Comparison of performance metrics with digital 2D versus tomosynthesis mammography in the diagnostic setting, Eur. Radiol. **29** (2019) 477–484.
[99] CHONG, A., WEINSTEIN, S.P., MCDONALD, E.S., CONANT, E.F., Digital breast tomosynthesis: Concepts and clinical practice, Radiol. **292** (2019) 1–14.
[100] LAI, Y.C., et al., Microcalcifications detected at screening mammography: Synthetic mammography and digital breast tomosynthesis versus digital mammography, Radiol. **289** 3 (2018) 630–638.
[101] DIEKMANN, F., et al., Evaluation of contrast-enhanced digital mammography, Eur. J. Radiol. **78** 1 (2011) 112–121.
[102] SOGANI, J., et al., Comparison of background parenchymal enhancement at contrast-enhanced spectral mammography and breast MR imaging, Radiol. **282** 1 (2017) 63–73.
[103] JOCHELSON, M.S., LOBBES, M.B., Contrast-enhanced mammography: State of the art, Radiol. **299** (2021) 36–48.
[104] YAFFE, M.J., et al., The effect of mammography screening regimen on incidence-based breast cancer mortality, J. Med. Screen. **25** (2018) 197–204.
[105] SASLOW, D., et al., American cancer society guidelines for breast screening with MRI as an adjunct to mammography, CA Cancer J. Clin. **57** (2007) 75–89.
[106] KUHL, C.K., Abbreviated breast MRI for screening women with dense breast: The EA1141 trial, Br. J. Radiol. **91** 1090 (2018) 20170441.
[107] CHANG, C.H., et al., Computed tomography in detection and diagnosis of breast cancer, Cancer **46** (1980) 939–946.
[108] GISVOLD, J.J., REESE, D.F., KARSELL, P.R., Computed tomographic mammography (CTM), AJR Am. J. Roentgenol. **133** (1979) 1143–1149.
[109] CHEN, B., NING, R., Cone-beam volume CT breast imaging: Feasibility study, Med. Phys. **29** (2002) 755–770.
[110] CHEN, Z., NING, R., Why should breast tumour detection go three dimensional? Phys. Med. Biol. **48** (2003) 2217–2028.
[111] BOONE, J.M., NELSON, T.R., LINDFORS, K.K., SEIBERT, J.A., Dedicated breast CT: Radiation dose and image quality evaluation, Radiol. **221** (2001) 657–667.
[112] LINDFORS, K.K., et al., Dedicated breast CT: Initial clinical experience, Radiol. **246** (2008) 725–733.
[113] KALENDER, W.A., et al., Technical feasibility proof for high-resolution low-dose photon-counting CT of the breast, Eur. Radiol. **27** (2017) 1081–1086.
[114] BERGER, N., MARCON, M., FRAUENFELDER, T., BOSS, A., Dedicated spiral breast computed tomography with a single photon-counting detector: Initial results of the first 300 women, Invest. Radiol. **55** (2020) 68–72.
[115] MONNIN P., et al., A comparison of the performance of modern screen-film and digital mammography systems. Phys Med Biol. Jun 7 **50** (11) (2005) 2617-2631.
[116] MONNIN, P., GUTIERREZ, D., BULLING, S., GUNTERN, D., VERDUN, F.R., A comparison of the performance of digital mammography systems, Med. Phys. **34** (2007) 906–914.

[117] THIERENS, H., et al., Type testing of physical characteristics of digital mammography systems for screening within the Flemish breast cancer screening programme, Eur. J. Radiol. **70** (2009) 539–548.
[118] VAN ONGEVAL, C., et al., Evaluation of the diagnostic value of a computed radiography system by comparison of digital hard copy images with screen-film mammography: results of a prospective clinical trial, Eur. Radiol. **16** (2006) 1360–1366.
[119] FABISZEWSKA, E., GRABSKA, I., JANKOWSKA, K., SKRZYŃSKI, W., ŚLUSARCZYK-KACPRZYK, W., Evaluation of the quality of mammographic screening examinations performed in the Mazovian province in 2007–2009, Pol. J. Radiol. **76** (2011) 77–80.
[120] ŚLUSARCZYK-KACPRZYK, W., SKRZYŃSKI, W., FABISZEWSKA, E., Evaluation of doses and image quality in mammography with screen-film, CR, and DR detectors — Application of the ACR phantom, Pol. J. Radiol. **81** (2016) 386–391.
[121] KALATHAKI, M., et al., Comparison of full field digital (FFD) and computed radiography (CR) mammography systems in Greece, Radiat. Prot. Dosim. **147** (2011) 202–205.
[122] MORA, P., et al., Latin American image quality survey in digital mammography studies, Radiat. Prot. Dosim. **174** (2017) 94–101.
[123] DA SILVA, S.D., et al., Dosimetry and image quality in digital mammography facilities in the State of Minas Gerais, Brazil, Radiat. Phys. Chem. **116** (2015) 292–299.
[124] DANTAS, M.V., Dose glandular e controle de qualidade da imagem em servicos de mamografía com sistema de radiografia computadorizada, Centro de Desenvolvimento de Tecnologia Nuclear, Pampulha, Brazil (2010).
[125] GAONA, E., RIVERA, T., MOLINA-FRECHERO, N., FRANCO, J.G., Exploratory survey of initial image quality in new digital mammography units prior to use in patients in Mexico, Appl. Radiat. Isot. **141** (2018) 266–269.
[126] GAONA, E., et al., Exploratory survey of image quality on CR digital mammography imaging systems in Mexico, Appl. Radiat. Isot. **83** (2014) 245–248.
[127] BRANDAN, M., et al., Overall performance, image quality, and dose, in computed radiology (CR) mammography systems operating in the Mexican public sector, Proc. SPIE 11513, 15th International Workshop on Breast Imaging (IWBI2020), 115131J (2020).
[128] COUNCIL OF THE EUROPEAN UNION, Council directive 2013/59/EURATOM of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation and repealing Directives 89/618/EURATOM, 90/641/EURATOM, 96/29/EURATOM, 97/43/EURATOM and 2003/122/EURATOM. Off. J. Eu. Union (2014).
[129] CARUANA, C.J., et al., EFOMP policy statement 16: The role and competences of medical physicists and medical physics experts under 2013/59/EURATOM, Phys. Med. **48** (2018) 162–168.
[130] BOSMANS, H., et al., Confrontation of mammography systems in Flanders with the European guidelines for quality assurance in mammography screening. Analysis of initial results, JBR-BTR **82** 6 (1999) 288–293.

[131] BINST, J., et al., 15 years of remotely controlled daily quality control in digital mammography, Proc. SPIE 11513, 15th International Workshop on Breast Imaging (IWBI2020) (2020).
[132] INTERNATIONAL ATOMIC ENERGY AGENCY, Implementation of a Remote and Automated Quality Control Programme for Radiography and Mammography Equipment, IAEA Human Health Series No. 39, IAEA, Vienna (2021).
[133] BOITA, J., et al., Development and content validity evaluation of a candidate instrument to assess image quality in digital mammography: A mixed-method study, Eur. J. Radiol. **134** (2021) 109464.
[134] MARSHALL, N.W., MONNIN, P., BOSMANS, H., BOCHUD, F.O., VERDUN, F.R., Image quality assessment in digital mammography: Part I. Technical characterization of the systems, Phys. Med. Biol. **56** (2011) 4201–4220.
[135] BLOOMQUIST, A.K., MAINPRIZE, J.G., MAWDSLEY, G.E., YAFFE, M.J., A task-based quality control metric for digital mammography, Phys. Med. Biol. **59** (2014) 6621–6635.
[136] WIGATI, K.T., et al., On the relevance of modulation transfer function measurements in digital mammography quality control, J. Med. Imag. **8** 2 (2021) 023505.
[137] LOOS, C., BUHR, H., BLENDL, C., Investigation of the performance of digital mammographic X ray equipment: Determination of noise equivalent quanta (NEQQC) and detective quantum efficiency (DQEQC) compared with the automated analysis of CDMAM test images with CDCOM and CDIC programs, Rofo. **185** 7 (2013) 635–643.
[138] WARREN, L.M., et al., Effect of image quality on calcification detection in digital mammography, Med. Phys. **39** (2012) 3202–3213.
[139] PUBLIC HEALTH ENGLAND, National Health Service (NHS) Breast Screening Programme Equipment Report: Technical evaluation of siemens revelation digital mammography system in 2D mode, PHE, London (2019).
[140] AMERICAN ASSOCIATION OF PHYSICISTS IN MEDICINE, Development of a new universal breast dosimetry method (TG282), AAPM Task Group No. 282, AAPM, College Park, MD (2021).
[141] AMERICAN ASSOCIATION OF PHYSICISTS IN MEDICINE, Radiation dosimetry in digital breast tomosynthesis: AAPM Task Group No. 223, Med. Phys. **41** (2014) 091501.
[142] WADDEN, N.A.T., HAPGOOD, C., Canadian Association of Radiologists mammography accreditation program-clinical image assessment, Can. Assoc. Radiol. J. **15** (2021) 8465371211025195.
[143] NORMA OFICIAL MEXICANA NOM-041-SSA2-2011, Para la prevención, diagnóstico, tratamiento, control y vigilancia epidemiológica del cáncer de mama. DOF 09/06/2011 (2011).
[144] FOOD AND DRUG ADMINISTRATION, Guidance for Industry and FDA Staff: Mammography facility surveys, mammography equipment evaluations, and medical physicist qualification requirements under mammography quality standards act (MQSA), Rockville, MD, 20852 (2005).
[145] HENDERSON, L.M., et al., Characterizing the mammography technologist workforce in North Carolina, J. Am. Coll. Radiol. **12** (2015) 1419–1426.

[146] INTERNATIONAL ATOMIC ENERGY AGENCY, Roles and Responsibilities, and Education and Training Requirements for Clinically Qualified Medical Physicists, IAEA Human Health Series No. 25, IAEA, Vienna (2013).
[147] INTERNATIONAL ATOMIC ENERGY AGENCY, Clinical Training of Medical Physicists specializing in Diagnostic Radiology, Training Course Series No. 47, IAEA, Vienna (2010).
[148] INTERNATIONAL ATOMIC ENERGY AGENCY, Guidelines for the Certification of Clinically Qualified Medical Physicists, Training Course Series No. 71 IAEA, Vienna (2021).
[149] SIMEONOV, G., European activities in radiation protection in medicine, Radiat. Prot. Dosim. **165** (2015) 34–38.
[150] EUROPEAN SOCIETY OF RADIOLOGY, Summary of the European Directive 2013/59/Euratom: Essentials for health professionals in radiology, Insights Imag. **6** (2015) 411–417.
[151] EUROPEAN COMMISSION, Radiation Protection No 174. European Guidelines on Medical Physics Expert, Publications Office of the European Union, Luxembourg (2014).
[152] CARUANA, C.J., CHRISTOFIDES, S., HARTMANN, G.H., European Federation of Organisations for Medical Physics (EFOMP) policy statement 12.1: Recommendations on medical physics education and training in Europe, Phys. Med. **30** (2014) 598–603.

ABBREVIATIONS

^{18}F-FDG	18F-fluoro-2-deoxy-D-glucose
AAPM	American Association of Physicists in Medicine
ACR	American College of Radiology
AEC	automatic exposure control
AGD	average glandular dose
CAR	Canadian Association of Radiologists
CDMAM	contrast detail mammography
CEDM	contrast-enhanced digital mammography
CPD	continuing professional development
CQMP	clinically qualified medical physicist
CR	computed radiography
CRM	computed radiography for mammography
DBT	digital breast tomosynthesis
DDM	direct digital mammography
DICOM	digital imaging and communications in medicine
DMIST	digital mammographic imaging screening trial
DQE	detective quantum efficiency
DR	digital radiography
EQF	European Qualifications Framework
EUREF	European Reference Organisation for Quality Assured Breast Screening and Diagnostic Services
FDA	Food and Drug Administration (USA)
IEC	International Electrotechnical Commission
LMIC	low- and middle-income country
MAP	mammography accreditation programme
mAs	milliampere-seconds
MGD	mean glandular dose
MLO	mediolateral oblique
MQSA	mammography quality standards act
MRI	magnetic resonance imaging
MTF	modulation transfer function
NHS	National Health Service
PACS	picture archiving and communication system
PET	positron emission tomography
PMMA	polymethyl methacrylate
QAP	quality assurance programme
SDNR	signal difference to noise ratio
SFM	screen-film mammography

TCO	total cost of ownership
UPS	uninterruptable power supply
WHO	World Health Organization

GLOSSARY

automatic exposure control (AEC). A feature on a mammography system where an X ray sensor is used during the X ray exposure to terminate the X ray exposure when it is inferred that an appropriate amount of X rays has been absorbed by the detector to produce a high quality image. The simplest systems control only the exposure time in this way, while more sophisticated systems use additional information such as breast thickness and composition to control the kilovoltage and the target/filter combination to further optimize the X ray beam.

clinically qualified medical physicist (CQMP). A health professional with specialist education and training in the concepts and techniques of applying physics in medicine and competent to practise independently in one or more of the subfields (specialties) of medical physics (e.g. diagnostic radiology, radiation therapy and nuclear medicine) as assessed by the State that has a formal mechanism for registration, accreditation or certification.

computed radiography for mammography (CRM). Technology for mammographic imaging that uses multiple interchangeable, reusable detector plates coated with photostimulable phosphor material.

direct digital mammography (DDM). Technology for mammographic imaging in which the digitized signal of an electronic detector is an integral component of a mammography system.

mean glandular dose (MGD) or **average glandular dose (AGD)**. An estimate of the average absorbed dose to the fibroglandular tissue of a breast during imaging to estimate the radiation risk to the breast due to the exposure.

medical radiation technologist. A health professional with specialist 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 (e.g. diagnostic radiology, radiation therapy and nuclear medicine) as assessed by the State that has a formal mechanism for registration, accreditation or certification. A wide variety of terms are used throughout the world for such health professional, such as radiographer, radiological technologist, nuclear medicine technologist and radiation

therapist. The term ‘medical radiation technologist’ is used as the generic term in this document.

screen-film mammography (SFM). Technology for mammographic imaging that uses a conventional (analogue) receptor that contains an intensifying screen and X ray film processed with darkroom chemicals.

CONTRIBUTORS TO DRAFTING AND REVIEW

Bosmans, H.	Katholieke Universiteit Leuven, Belgium
Brandan, M.E.	National Autonomous University, Mexico
Castillo-López, J.P.	Instituto Nacional de Cancerología, Mexico
Ciraj Bjelac, O.	International Atomic Energy Agency
Cruz-Hernández, J.C.	Centro Nacional de Equidad de Género y Salud Reproductiva, Mexico
Delis, H.	International Atomic Energy Agency
Jong, R.A.	University of Toronto, Canada
Moreno-Ramírez, A.	Centro Nacional de Equidad de Género y Salud Reproductiva, Mexico
Tsapaki, V.	International Atomic Energy Agency
Vassileva, J.	International Atomic Energy Agency
Villaseñor-Navarro, Y.	Instituto Nacional de Cancerología, Mexico
Yaffe, M.	University of Toronto, Canada
Yeong, C.H.	University of Malaya, Malaysia

Consultancy Meetings

Vienna, Austria: 3–17 November 2017 and 13–17 August 2018

IAEA
International Atomic Energy Agency

No. 26

ORDERING LOCALLY

IAEA priced publications may be purchased from the sources listed below or from major local booksellers.

Orders for unpriced publications should be made directly to the IAEA. The contact details are given at the end of this list.

NORTH AMERICA

Bernan / Rowman & Littlefield
15250 NBN Way, Blue Ridge Summit, PA 17214, USA
Telephone: +1 800 462 6420 • Fax: +1 800 338 4550
Email: orders@rowman.com • Web site: www.rowman.com/bernan

REST OF WORLD

Please contact your preferred local supplier, or our lead distributor:

Eurospan Group
Gray's Inn House
127 Clerkenwell Road
London EC1R 5DB
United Kingdom

Trade orders and enquiries:
Telephone: +44 (0)176 760 4972 • Fax: +44 (0)176 760 1640
Email: eurospan@turpin-distribution.com

Individual orders:
www.eurospanbookstore.com/iaea

For further information:
Telephone: +44 (0)207 240 0856 • Fax: +44 (0)207 379 0609
Email: info@eurospangroup.com • Web site: www.eurospangroup.com

Orders for both priced and unpriced publications may be addressed directly to:

Marketing and Sales Unit
International Atomic Energy Agency
Vienna International Centre, PO Box 100, 1400 Vienna, Austria
Telephone: +43 1 2600 22529 or 22530 • Fax: +43 1 26007 22529
Email: sales.publications@iaea.org • Web site: www.iaea.org/publications

Digital mammography offers fundamental advantages over film based mammography. These include the possibility for acquiring quality images at lower radiation dose image recording, processing and archiving as well as the use of artificial intelligence for improving diagnostic outcome. Other practical advantages include cost reduction, use of environmentally friendly technology, and the option of obtaining remote expert diagnostic opinion. Image quality in mammography is critical. A switch from screen-film technology to a digital system is preferable only if high quality images can be guaranteed. This publication provides guidance on the establishment of digital mammography facilities and the upgrade of existing facilities. It focuses on planning, designing and operating the high quality mammography service within available resources.

IAEA HUMAN HEALTH SERIES

INTERNATIONAL ATOMIC ENERGY AGENCY
VIENNA