

**THE EVALUATION OF THE PERFORMANCE OF THE AUTOMATIC  
EXPOSURE CONTROL SYSTEM OF SOME SELECTED MAMMOGRAPHY  
FACILITIES IN THE GREATER ACCRA REGION, GHANA**

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## DECLARATION

This thesis is the result of research work undertaken by Richard Amesimenu in the Department of Nuclear Safety and Security, School of Nuclear and Allied Sciences, University of Ghana, under the supervision of Dr. Mary Boadu and Prof. Cyril Schandorf

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## LIST OF ABBREVIATION

AEC	Automatic Exposure Control
ACR	American College of Radiology
ALARA	As Low As Reasonable Achievable
BSc	Bachelor of Science
BSE	Breast Self Examination
CC	Craniocaudal View
CBE	Clinical Breast Examination
ESAK	Entrance Surface Air Kerma
EU	European Union
FDA	Food and Drug Administration
GAEC	Ghana Atomic Energy Commission
HVL	Half Value Layer
IAEA	International Atomic Energy Agency
ICRP	International Commission of Radiological Protection
kV	Kilovoltage
lp/mm	Line pairs per millimeter
mAs	Milliampere seconds
mGy	Milligray
mR	milliRoentgen
MLO	Mediolateral Oblique View
MGD	Mean Glandular Dose
Mo/Mo	Molybdenum/Molybdenum
Mo/Rh	Molybdenum/Rhodium

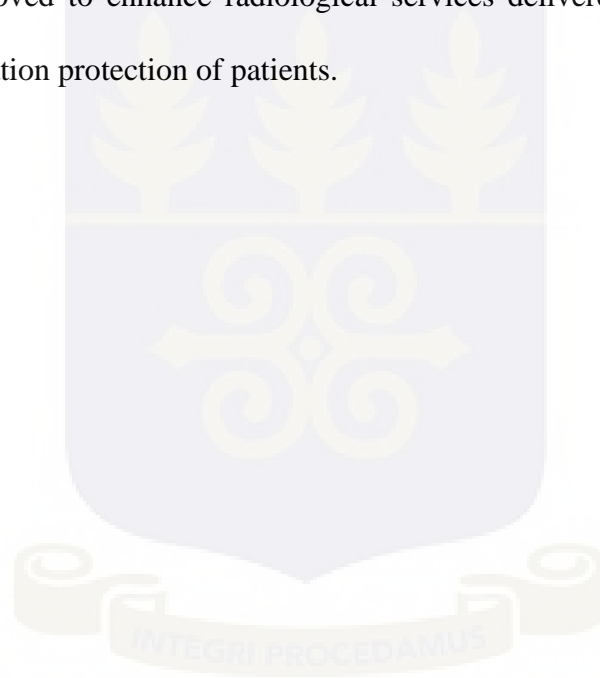
NHSBSP	National Health Service Breast Screening Programme
OD	Optical Density
PMMA	Polymethyl Methacrylate.
ROI	Region of Interest
RPB	Radiation Protection Board
RPI	Radiation Protection Institute
QMS	Quality Management System
CT	Computed Tomography
QA	Quality Assurance
QC	Quality Control



## ABSTRACT

Mammography aids in the early detection of breast cancer. X-rays has an associated risk of inducing cancer though very useful and as such mammography procedures should be optimized through the appropriate processes such as the selection of exposure factors for an optimum image and minimal dose to patients. The automatic exposure control (AEC) aids in the selection of exposure factors thus controlling the amount of radiation to the breast and automatically compensates for differences in breast thickness and density. The performance of the automatic exposure control system of mammography equipment and the status of quality management systems including quality assurance and quality controls of four (4) mammography facilities within the Greater Accra Region were assessed. In assessing the performance of the automatic exposure control system, the short term reproducibility test, thickness and voltage compensation tests were carried out using breast equivalent phantom of various thicknesses. Half value layer test, film reject analysis and patient dose assessment were also performed. Analysis of the responses of the questionnaire administered to radiographers and supervisors of the selected facilities revealed that three (3) of the facilities have some aspect of a quality management system programme in place but not effectively implemented. Measured optical densities from the various tests performed to evaluate the performance of the automatic exposure control systems revealed that the AEC compensates for the different phantom thicknesses and tube voltages (kV) by producing comparable optical densities for the various phantom thicknesses and tube voltages. Some of the measured optical densities were within the recommended optical density range of 1.5 OD – 1.9 OD. The highest optical density value was 0.13 OD above the highest limit of 1.9 OD. The film reject analysis showed that patient motion accounted for the larger part (28 %) of film rejects. Other factors such

as too light or too dark films also accounted for film reject signifying the need for continuous training for radiographers and an effective quality control programme. Estimated mean glandular dose (MGD) of values 1.0 mGy, 1.3 mGy, 1.1 mGy and 1.1 mGy at 28 kV for the selected facilities were less than 2 mGy and 3 mGy per the recommendation of International Atomic Energy Agency (IAEA) and American College of Radiology (ACR) respectively. Management of mammography facilities must establish an effective quality management system which must be implemented and continually improved to enhance radiological services delivered to patients as well as improve the radiation protection of patients.



## CHAPTER ONE

### 1.0 Introduction

Mammography is the most utilized imaging technique for the early detection and diagnosis of breast cancer due to its optimum performance in detecting such cancers and less imaging time compared to other imaging techniques [1, 2, 3]. Studies have established that the early detection of breast cancer and appropriate patient management has some positive influence of reducing breast cancer related deaths and this has translated into the decrease in mortality rate due to breast cancer amongst women [4, 5, 6]. Breast cancer on the other hand is the most common cancer and the leading cause of cancer deaths in women [7, 8, 9].

During a mammography procedure, low energy x-ray radiation between the range of 25-35 kVp are used to examine the human breast most especially the female breast to identify cancerous tissues or any unusual structures within the breast observed during breast screening which consists of breast self examination (BSE) and clinical breast examination (CBE)[9, 10]. Mammography procedures are performed on asymptomatic and symptomatic women thus screening and diagnostic mammography procedures respectively. Since breast cancer has no symptoms at its early stage, asymptomatic women who are at a risk of developing some form of breast cancer due to their age i.e. above 40 years are screened to detect any cancer or related breast disease before symptoms begin to manifest. For symptomatic women that is women who show signs of the breast cancer and breast related diseases such swelling, pains and lumps within the breast or patients referred by a medical doctor to a mammography centre or hospital,

diagnostic mammography procedure is used to confirm the presence of breast cancer tissue, the type of lump or the source of pain identified by the medical doctor or during screening mammography examination [1, 11].

The use of x-rays for medical diagnosis and treatment of diseases such as breast cancer has small but significant associated risk of inducing cancers in humans. The rate of the cancer inducement is enhanced by frequent exposure to x-rays through radiological procedures. Though mammography is currently the best screening and diagnostic tool for breast cancer, it also has some associated risks due to the use of x-rays [11, 12]. The human breast is mostly made up of glands (mammary glands) and adipose tissue, of which the mammary glands are most sensitive to radiation and are at a greater risk of developing cancer (breast cancer) compared to the adipose tissue [9]. Due to this, assessment of mean glandular dose which is dose delivered to the breast during an examination is an integral and required part of the quality control programme that must be performed by all facilities using x-rays for medical and other purposes as captured in most studies and procedures [10, 13, 14].

Quality control programme and dose assessment for that matter give an insight into the level of radiation received by patients undergoing examination and the corrective actions required if radiation levels are beyond or below acceptable levels and standards. In applying the basic principles of radiological protection of patients as recommended by the International Commission of Radiological Protection (ICRP) which are justification of the procedure, that is the benefits associated with the procedure must outweigh the risks related to the procedure and optimization of protection which also implies that radiation exposure to patients undergoing treatment or diagnosis must be kept as low as

possible while producing quality images for adequate diagnosis [11]. Effective quality control programme is therefore an essential part of a quality management system programme that deals with the instrumentation and equipment used for procedures to be established and implemented in accordance with standards. A quality control programme is also used in assessing and monitoring technical details within the systems that have some effects on the quality of images as well as patient dose including the evaluation of the performance of the automatic exposure control system. Patient dose and image quality can be altered by the slightest change in the normal function and correct use of instrument, equipment and devices such as the automatic exposure control system. A well established and implemented quality control programme ensures the production of high quality images, which eventually optimizes the diagnostic outcome of radiological procedures such as mammography.

Though small amount of radiation is associated with mammography procedures compared to other radiological examinations it is in line with the principle of optimization that the amount of radiation exposure to patients be reduced to as low as reasonably achievable. Manufacturers of radiological equipment used for radiological examination such as the mammography equipment and scientists are aware of the biological effects associated with x-rays on humans and therefore try to design and modify such equipment to help minimize radiation to patients and operators during examinations or procedures to the least for the same quality images. Such design and modifications include the installation of automatic exposure control systems on equipment such as the mammography equipment to regulate the amount of radiation exposures to patients undergoing procedures while producing an optimal or quality image

deemed adequate for diagnosis so that the consequences associated with poor image quality and interpretation such as repeat of procedures, unnecessary exposures and cost to patients are annulled. Factors that affect image quality and patient dose include the tube voltage (kV), thickness of breast, x-ray beam filtration(filter material), target material, choice of film and screen, breast positioning and compression and tube current [15, 16].

The automatic exposure control (AEC) also known as photo-timer is a type of circuit timer just like the mAs timer and mechanical timer made up of detector(s). For mammography equipment the AEC is normally situated underneath the cassette and its function is to control the amount of radiation exposure to the image receptor by terminating the x-ray exposure when the suitable optical density of the film and predetermined amount of radiation are attained [17, 18, 19]. The AEC also automatically manages the selection of technical factors such as the filter material, mAs, time, kV or a combination of any or all of factors depending mostly on the type of AEC design of the equipment [19]. The dose at which the AEC terminates exposure is directly proportional to the mean glandular dose that is dose delivered to the breast during an examination [14].

The automatic exposure control system aids in the production of consistent and accurate mammograms consequently decreasing the rate of repeating procedures and hence dose to patients undergoing the examination. The position of the part of the patient i.e. breast over the AEC detector(s) and the selection of the appropriate detector are some of the parameters that affect the performance of the automatic exposure control system.

The short term reproducibility, object thickness compensation and tube voltage compensation tests are tests carried out to determine the performance of the automatic exposure control system [11].

This work will focus on the performance of the mammography's automatic exposure control system with reference to the production of consistent and high quality image to ease interpretation whiles keeping radiation exposure to patients as low as possible. This will be done for mammography system in some selected mammography centres in Accra.

### **1.1 Statement of the problem**

An ineffectively implemented quality management system by the administration can have some negative effect in the good delivery of radiological services to patients which could be as a result of poor quality control and quality assurance programme. In mammography procedures, the production of constantly high quality images and effective delivery of services to patients are amongst the important aims of an effectively implemented quality management system including quality control. It also enhances the ALARA principles of reducing doses while producing an optimum image adequate enough for diagnosis. To successfully realize this, the performance of the mammography equipment and imaging procedures needs to be optimized. To this effect, the automatic exposure control system is used to automatically control the selection of exposure factors during procedures thus controlling the amount of radiation to the patient. To ensure the effective functioning of the AEC, its performance must be evaluated during quality control procedures which must be in line with the baseline parameters such as the target optical density established during the commissioning and acceptance tests.

This study seeks to research into the performance of AEC with regards to the prescribed standard of mammography machines that use the AEC during examination and the quality management system in place in these facilities.

## **1.2 Objectives of the study**

The main objective of this study is to assess the performance of automatic exposure control system of mammography equipment of some facilities undertaking mammography procedures to verify compliance with current international standards pertinent to optimization of patient radiation protection.

The specific objectives are:

- Assess the status of quality management systems programmes in mammography procedure in the selected mammography facilities.
- Analyze and compare image quality of facilities whose radiographers use AEC systems during breast examinations to facilities that do not use AEC systems during breast examinations.
- Determine patient dose (mean glandular dose) of selected facilities and compare them to the international standards.
- Make verification checks of some quality control parameters that affect image quality and patient dose including film reject analysis.
- Make appropriate recommendations to (i) Hospital and centres (facilities) authorities and (ii) Regulatory Authority (Radiation Protection Board (RPB)) from the findings of this study.

### **1.3 Scope**

The study examined the performance of the automatic exposure control systems used by the operators of mammographic equipment in mammography facilities by verifying if their performance and output meets international standards. Also the potential of dose reduction and the possibility of producing and maintaining quality image using the automatic exposure control systems during procedures were assessed. This was done by comparing facilities whose operators use the automatic exposure control and those that do not use the automatic exposure control systems for imaging procedures. Quality management systems in place in the various mammography facilities were also examined.

The study was carried out in (4) four mammography facilities/centers within Greater Accra.

### **1.4 Relevance of the project work**

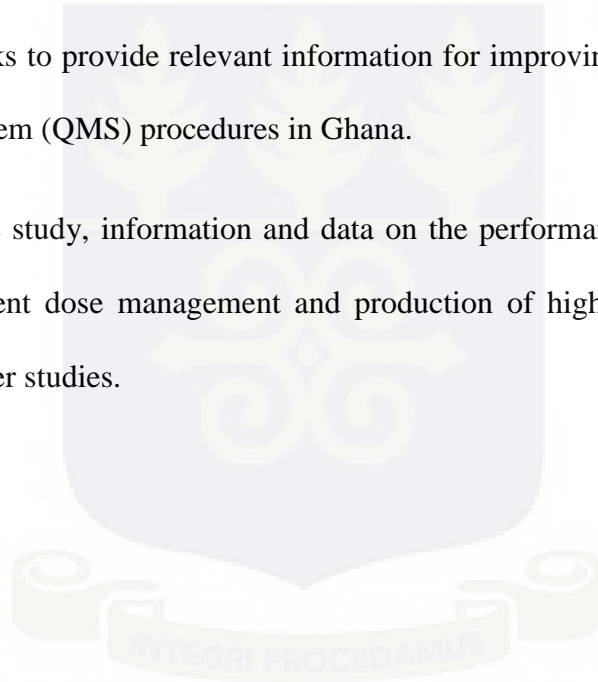
Mammography just like other radiological techniques needs to be performed and interpreted with maximum quality. The AEC system aids in producing consistent quality images while reducing patient dose. When the AEC is not used properly it leads to avoidable exposures to patients during procedures as well as necessitating repeat of procedures thus increasing patient dose. Improper usage including poor positioning of patient's breast over the AEC detector as well as the incorrect selection of the detector can result in the early or delayed termination of exposure resulting in over or underexposure of the patient.

On the whole and in order to protect patients undergoing breast examinations from unnecessary and preventable exposures and to ascertain that the operation and output of the AEC systems are within acceptable standards, the performance of these automatic exposure control systems is required.

An initial survey indicated that assessing the performance of AEC during acceptance testing of mammography equipment by facilities before being used for clinical purposes have not been done for some of the mammography equipment in operation.

The research seeks to provide relevant information for improving mammography quality management system (QMS) procedures in Ghana.

At the end of the study, information and data on the performance of such devices with reference to patient dose management and production of high quality images may be relevant for further studies.



## CHAPTER TWO

### LITERATURE REVIEW

#### 2.0 Introduction

With reference to published literatures, this chapter outlines some elements of diagnostic radiography, mammography procedures, types of mammography procedures, types of mammography equipment, automatic exposure control system (AEC) and factors that affects image quality and patient dose. Other details include information on mammography dosimetry and quality management system.

#### 2.1 Diagnostic Radiography

Diagnostic radiology is amongst the medical practices that involve exposures from ionizing radiation due to its ability to penetrate the human body. The densities of the various internal body structures result in the attenuation of x-rays as they pass through the body (expose) resulting in the darkening of a photographic film after it is processed. This property of the x-ray on the human body has enabled man to use it for medical purposes such as verifying and locating abnormalities or faults within any part of the human body via the images produced using the x-rays. Procedures involving the use of the x-rays for analysis include mammography; imaging the breast, plain radiography; imaging the chest or bone in any other part of the body i.e. the leg, fluoroscopy; imaging parts of the body and computed tomography (CT). With the aid of the images obtained from these procedures, radiologist and other medical physicians are able to provide the appropriate diagnosis.

Due to the harmful effects of x-rays on the human body, radiological equipment used for medical purposes in recent times compared to the early years of x-rays discovery and medical usage have been improved in terms of their radiation output and usage. These equipment are continuously developed and modified so as to maximum the benefits derived from the usage of x-rays while ensuring radiation protection of patients, operators (radiographers), the general public and the environment.

## **2.2 Mammography**

Mammography is the most useful and currently the best imaging procedure compared to other procedures for especially the screening and early detection of breast cancer and related diseases among women [1, 2, 3]. Mammography involves the use of a dedicated equipment which produces low energy x-rays in the range of 25-35 kV to examine the human breast to identify or confirm cancerous tissues or any unusual structure such as calcifications (microcalcifications and macrocalcifications), lumps and masses within the breast observed during self examination (BSE) and clinical breast examination (CBE)[9, 20 21]. The soft nature of the breast demands the use of low energy radiation during the procedure. The low energy radiation helps improve the contrast of the image as well as expose patients to lower doses of radiation compared to other imaging techniques though no small amount of radiation dose to human is risk free. There are basically two types of mammography procedures namely screening mammography and diagnostic mammography.

### **2.2.1 Screening Mammography**

Breast cancer exhibits no symptoms in its premature stages and that every woman above a certain age is at risk of developing breast cancer but its early detection can help in its treatment. In an effort to reduce breast cancer disease and mortality cases through its early detection, organizations and breast cancer and health programmes such as the American College Radiology (ACR), World Health Organization (WHO), European Commission (EU) and breast screening programmes promote and encourage the periodic screening of women, even if they show no symptoms of such cancer. Women are also educated on breast cancer diseases and related issues such as self hand examination, visual self inspection through breast cancer awareness programmes i.e. health seminars. According to studies, the early detection of breast cancer through periodic breast screening is the only method for reducing breast cancer deaths among women since it significantly enhances the probability for successful treatment [11].

Screening mammography is performed on asymptomatic women that is women who do not exhibit any symptoms of breast cancer and it involves the use of x-rays to examine the breast to find out any unusual structures or undetected breast cancer within the breast that cannot be detected through self examination or by the doctor before they develop fully into cancer [11, 20, 22]. Screening mammography also aids in the early detection of abnormal changes in the breast before they are noticed by the woman or a doctor [20, 22, 23].

### **2.2.2 Diagnostic Mammography**

Diagnostic mammography is a follow up procedure of screening mammography and involves the use of low energy x-rays to examine the breast of symptomatic women or women who show indications or symptoms of any form of breast disease or abnormality observed by the women or the doctor. Such procedures are also performed on patients referred by a clinician to a mammography centre to confirm the presence of breast cancer or any abnormality within the breast identified on the mammogram during screening mammography [1, 10, 20, 22]. Biopsy is normally conducted to confirm a cancerous tissue observed during diagnostic mammography.

### **2.3 Mammographic Views**

Due to the composition of the breast, when images of the breast are not captured well on the mammogram, radiologists tend to have some challenges in interpreting and providing accurate diagnosis. Therefore in-order to enable a radiologist have enough information to interpret mammograms correctly, images of the breast are captured in different types of views or directions. The different types of views performed mostly for screening mammography procedure and diagnostic mammography are the standard views.

#### **2.3.1 Craniocaudal View (CC)**

The craniocaudal view is one of the two standard types of views performed in screening and diagnostic mammography. Craniocaudal view visualizes areas of the breast where the mediolateral view is not able to visualize as well as show clearly the makeup or structures of the breast. For this type of view the breast rests on the image receptor making it more

relaxed and allows one breast to be sufficiently compressed as a result of which image blurring caused by patient motion is significantly minimized. The craniocaudal view enables the medial part to be adequately revealed as well as the external lateral portion of the breast [24].

For a craniocaudal view procedure the breast rests 180° on the breast support likewise the compression plate on the breast while the vertical x-ray beam is directed from the cranial to caudal (downward) through the breast [17]. A craniocaudal view is considered as good if the mammogram captures the medial fold of the breast, the lateral breast tissue, the nipple line and the entire body of the glandular tissue. An image of the breast being symmetrical is also regarded as a good view [24, 25].

### **2.3.2 Mediolateral Oblique View (MLO)**

The mediolateral view when taken, helps visualize the tissues adjacent to the chest wall and the auxiliary tail. This view is essential because majority of cancers occur in the auxiliary tail of the breast [24]. When well captured it offers the radiologist the best option of viewing most of the breast tissues within the breast. The mediolateral view also aids in the assessment of the suitable positioning of the breast.

In performing a mediolateral view the arm of the mammography equipment is adjusted at an angle of 45° or more to the breast. The breast is adequately compressed to prevent skin folds and movement of the patient. A mediolateral view is considered as high quality if the image is symmetrical and the glandular tissue is well distributed. Furthermore the entire breast and tissues and the nipple alongside the pectoral muscle are clearly shown in the mammogram [24, 25].

### **2.3.3 Other Supplementary Views**

Diagnostic mammography mostly involves the critical analysis area(s) of concern or region(s) of interest of the breast observed on the standard views (craniocaudal and mediolateral views) of the screening mammograms. In performing diagnostic mammography, in addition to the standard views, other images of different views are taken to provide satisfactory and sufficient information to enable careful study of the region(s) of interest or area(s) of concern of the breast for excellent diagnosis. The type of additional or supplementary view of the breast taken depends on the type of problem and its location in the breast.

Other supplementary views include the spot compression view, double spot compression view, magnification view, lateromedial view and step oblique views [26].

### **2.4 Screen - Film Mammography**

Screen film mammography involves capturing directly images of the breast with high detail intensifying screen onto a film. A mammography cassette which houses the film is in close contact with the intensifying screen [17].

During an examination the breast and a mammography film are exposed, after which the film is processed with a film processor to display the captured images of the breast.

The formation of the image on the film is in two stages; i) the x-ray beam emerging from the breast is transformed into a pattern of visible light by the cassette intensifying screen and (ii) the visible image is captured permanently on the film.

Some shortcomings of the screen - film mammography include; its sensitivity for the detection of breast cancer in denser breasts is reduced making it less helpful to high risk

women with thicker breast. It also has low specificity and this has resulted in patients undergoing unnecessary biopsies procedures because some detected lesions recommended for biopsy after the procedure turns out to be non cancerous. [27]. Furthermore, when images are directly captured on the films no alteration can be made to improve the image contrast and they cannot be stored directly on a storage device. The quality of the images reduces with time due to the effect of environmental conditions on the film such as temperature.

## **2.5 Digital Mammography**

Digital mammography involves the use of special design equipment during breast examination that has the ability to record and display captured images on a high resolution display monitor or screen.

Depending on the dimensional ability of the equipment i.e. 2-dimensional, other angles of the imaged breast can be viewed and this provides more information for enhancing mammography interpretation and diagnosis by the radiologist. Also specially designed computer softwares afford the modification of captured images such as modification of contrast before they are finally printed on a special film or put on a storage device. Compared to the screen-film mammography, digital mammography is noted to produce better images of dense breast thus making it the best choice for women with big and denser breasts [28] and repeat of procedures due to poor image is very low due to the ability to alter the captured image. However the cost procedure is more expensive for digital mammography.

Digital mammography affords the transfer and safe storage of images on storage devices such as hard disk and compact disk (CD) and the quality of stored images do not reduce with time.

## **2.6 Automatic Exposure Control (AEC)**

In an effort to control the amount of radiation to patients while producing quality images during procedures, mammography equipment are fitted with devices such as the automatic exposure control also known as automatic dose control. The function of the AEC is to automatically terminate exposures when the needed amount of radiation exposure to produce a mammogram of optimum optical density is attained. The AEC also aids radiographers in the production of consistent and accurate images irrespective of size and density of the breast when correctly used [29]. The AEC is made up of detectors and these detectors include ionization chambers and are normally fitted between the grid and the mammography cassette [30].

The advantages of using the AEC during procedures include decrease in repeat rate of examinations which is very significant in the optimization of procedures, decrease in patient and radiographer (staff) exposures and increase in operational efficiency of the facility. These benefits or advantages can be realized if the device is operated properly.

These devices are designed to automatically control and select one or more technique factors such as kVp, mAs and time during mammography procedures. These exposure factors influence the appearance of images and the amount of radiation delivered to patients. The selection of these technique factors depends on the AEC mode of the equipment which refers to the type of automatic exposure control fitted in the mammography equipment. AEC modes includes fixed kVp and mA (where the kVp and

mA are selected by the operator and the time is varied by the AEC), fixed kVp (where the kVp is selected by the operator and the mAs is varied by the AEC) and the factors are selected and varied by the AEC with reference to the size, density, thickness and composition of the breast. The performance of the automatic exposure control system can be assessed by some quality control tests including the short term reproducibility test, thickness and voltage compensation tests. A research work was carried out to assess the automatic exposure system by measuring the optical densities of exposed films with reference to the position of the detector. Mean measured optical densities were between the range 1.47 OD to 1.70 OD [18].

For its operation, when x-rays from the tube are strike the detectors of the AEC, the detectors respond by producing small electric current which are then directed through a buffer amplifier. This leads to the accumulation of charges on the capacitor which is proportional to the amount of radiation present in the incident x-ray beam. When the accumulated charges attain the preset reference voltage, the voltage comparator outputs activates the exposure termination control which in-turn switches off the high voltage to the x-ray tube terminating the exposure. A density control which is part of the AEC system setup is able to alter the state of the reference voltage either up or down to accommodate for various sizes of the breast whiles maintaining a consistent response over the clinical kVp range [29]. The automatic control system has an in-built guard timer to terminate exposure in the event of system failure. It aids in preventing extreme over exposure of the breast.

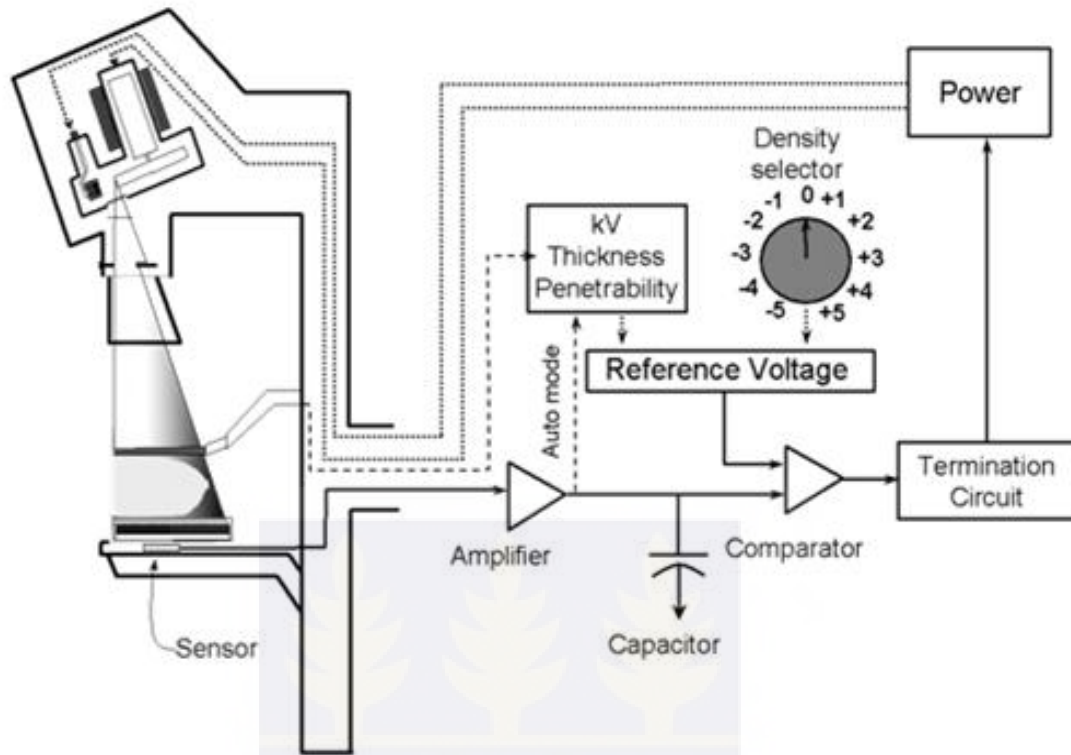


Fig 2.1 A circuit diagram of an automatic exposure control system [31]

### 2.6.1 Technique Chart

Before the design and incorporation of automatic exposure control devices to radiological equipment such as the mammography equipment, these equipment were operated manually by radiographers. Based on the characteristics of the breast (thickness, composition and size), the patient's history and radiographer's discretion, the exposure factors to produce an optimum image are manually selected.

To ensure that appropriate and consistent images are produced, the technique chart which contains values of the exposure factors that must be selected for a particular breast attributes is designed. The technique chart serves as a guide to radiographers in selecting the appropriate tube voltage (kV), tube load (mAs) and cassette size based on the

thickness and sizes of the breast so as to produce an optimum image while reducing the occurrence of repeat and overexposure or underexposure to patient [32].

It is recommended that every mammography unit should design a technique chart for the various breast sizes and thicknesses and a copy be part of a facility's quality control manual. A copy of the chart must be posted in the mammography equipment room to be visible to all persons, most especially the radiographer [10, 33, 34]. The chart should be periodically reviewed after any repairs, maintenance work or calibration of the x-ray system so as to ensure that the factors corresponding to the performance of the equipment selected are not changed.

## **2.7 Factors that affect Image quality**

Optimum image quality is critical in mammography procedures and other radiological procedures. An image will be classified as optimum if it has adequate contrast, sharpness, zero noise and no artifacts. These characteristics are affected by the choice of exposure factors such as kV, mAs, equipment design, imaging technique and quality assurance programme being implemented by the Mammography Facility. The fundamental primary factors of image quality are contrast, noise and unsharpness [35, 36].

### **2.7.1 Contrast**

The anatomy of the breast is mainly soft tissues with similar densities and low contrast. In-order to produce an image with highest details for a structure such as the breast it must have a high contrast. The contrast of an image is that important aspect or characteristics

of an image that enables two or more areas or structures on a radiograph or mammogram to be differentiated due to the level or degree of density difference. The better the contrast the more discerning the structures or features become [36, 37].

Contrast performance is affected by densities of the material being imaged, film processing condition (chemistry and concentration of processing chemicals and developing time), the target material of the x-ray tube and tube voltage (kV) setting. The others are scattered radiations and usage of an anti scatter grid during a procedure [36, 38].

The densities of the structures determine the absorption difference of the various structures within the breast or the human body. In order to produce a high contrast, parts of the body i.e. bone or structure will need a relatively high energy. The higher the density differences between the structures the better the contrast of the radiograph [39].

An increase in scatter radiations will lower the contrast of the image and vice versa. This effect can be reduced by adequately compressing the breast and using an anti scatter grid during an exposure. Using the grid during exposure though increases the quantity of radiation to the patient it reduces the scatter radiation thus improving image contrast [11, 40]. From literature, using molybdenum/molybdenum target filter combination during a procedure produces an outstanding image contrast [41]. Using high kV provides more penetration and produces more scatter radiation leading to low contrast resulting from the presence of fog and vice versa [42]. The type of film, its density, how the film is exposed, the chemistry and concentration of processing chemicals, temperature used to process the film, and the developing time also have some bearing on the contrast of the

image. To obtain an optimum contrast the right arrangements, balance and choices of these factors must be made.

### **2.7.2 Noise**

Noise is the visible grain like structures or variations that are not related to the material being imaged but appears on an image reducing the visibility and quality of the image [43]. Noise can manifest in three forms namely the electronic noise, structural noise and quantum noise. The quantum noise is noted to be a major source of noise in imaging procedures [44, 45, 46]. By increasing the amount of exposure or the concentration of the photons during a procedure, quantum noise can be reduced. Elements contributing to image noise are film granularity, structure noise from screen, screen and film parameters and the use of anti scatter grid. The x-ray films used for radiological procedures are made up of silver halides which turn to darken when the film interacts with radiation and developed. Film granularity are grain like structures on the image which is as a results of developed silver halide grains in the emulsion randomly distributed over the x-ray film.

### **2.7.3 Unsharpness**

Unsharpness is that feature of an image that makes the image blurred or unclear. Features contributing to the image sharpness are grouped under two factors namely geometric factors and film/screen factors. The geometry of the source, detector and patient with reference to the focal spot size of the x-ray tube affects the sharpness of an image. The geometric factors include the focal spot size, source to film distance, source to detector distance, angle between the source and movement of the patient during the exposure. The

film/screen factors also include type of film (grain size), wavelength of the primary radiation and developing time and other processing factors [47].

To produce an optimum sharp image good for diagnosis, the source to detector distance should be large and similarly the focal spot size should be as small as possible and must be within the range set for adequate exposure from the x-ray tube. The patient or area of interest to the detector distance should be also small. Movement during an exposure by the patient, source or detector will affect the sharpness of the image. Movement of any form by the patient should be reduced to ensure an optimum image is produced.

The film/screen combination involves the use of a single screen in contact with the emulsion layer of a single film, thus to increase image sharpness there must be a good contact between the screen and the film emulsion. A fine grain film if exposed correctly will produce a sharp image compared to a coarse grain film.

### **2.8 Factors that affect Patient Dose**

Image quality forms an integral part of mammography and other radiological procedures. An optimum image will aid in the effective interpretation of images translating into the provision of good diagnosis [48]. The breast is composed of very soft tissues such as the glandular tissues, fatty and fibrous tissues necessitating the use of low energy radiation during procedures to enable those structures to be seen and differentiated from each other on a mammogram. The reduction or attenuation coefficients due to the glandular and fatty tissues are comparable. Similarly the density difference between a normal or disease free and abnormal breast tissue is very small [7].

During radiological procedures such as mammography there are some factors such as the x-ray beam quality that have influence on the radiation delivered to the patient and the quality of the image produced at the end of the procedure [49]. When the factors are well selected and balanced they positively impact on the patient dose and image quality.

### **2.8.1 Tube Voltage (kV)**

The tube voltage (kV) is one of the most significant factors which affects exposures to patients and the production of quality images adequate for diagnosis. In the production of x-rays, the x-ray photons produced after the interaction of the high speed electrons and the target material are determined and controlled by the tube voltage (kV) that is the energies of photons in the beam. The energies of these photons illustrate the rate or speed at which they move from the x-ray tube and penetrate objects. Increasing the kV value results in the increase of speed and the number of x-rays produced and this reduces exposure time and dose to the breast because the x-rays take less time to penetrate the breast.

A beam with very high tube voltage will reduce image contrast. It is essential to consider the size and density of the breast when selecting an appropriate kV. The thicker and denser the breast the higher the tube voltage value to produce more penetrating beams so exposure time and radiation dose to the breast is minimized though high kV produces a high radiation dose. Mammography compared to other technique is the only procedure that uses low energy photons or kV with values in the range 25 kV – 35 kV due to the soft tissues (adipose tissues) of the breast [50].

### **2.8.2 Filter Material**

The penetration of the breast by the x-rays and contrast of image produced is dependent on the x-ray beam filtration. The filter is an important part of the x-ray tube with a role of minimizing low and extremely high energy photons that are below or above the desired energy level needed for that particular procedure. The filter absorbs very low energy photons that do not have enough energy to infiltrate the breast before they get to the breast of the patient. These very low energy photons do not contribute to the formation of the image, but rather increases the quantity of radiation dose to the patient. The most commonly used filter material in mammography equipment is molybdenum (Mo) and it is normally selected when imaging normal size or less thick breast. Rhodium (Rh) is also another filter material used alongside the molybdenum in some equipment and is also best used during the imaging of thicker and denser breasts [9, 51].

### **2.8.3 Target Material**

The human breast is composed of very soft tissues making mammography procedures to employ low energy photons. Molybdenum (Mo) material with atomic number 42 is the most used anode material in mammography equipment because it produces enough characteristics x-rays compared to bremsstrahlung x-rays of suitable energy for mammography procedure. Rhodium (Rh) material of atomic number 45 is also another anode material fitted in the mammography equipment which also produces high and more penetrative energy x-rays essential for the imaging of dense breast. During x-ray production the major characteristics x-rays are produced at maximum kV of 17.5 and 19.6 keV for molybdenum, and 20.2 and 22.7 keV for rhodium respectively. Due to the

low atomic numbers of molybdenum and rhodium compared to tungsten material of atomic number 74, they are able to attain the needed contrast with the soft breast tissues [9, 52, 53].

#### **2.8.4 Tube current and Tube load**

The tube current relates to the current through the x-ray tube of the mammography equipment, and hence the number of x-ray photons produced from the x-ray tube. The tube load is the product of the tube current, (milliamperere, mA) and the exposure time (second, s) which is directly proportional to the radiation dose to the patient. Increasing the tube current therefore increases radiation dose to the patient [9, 13].

For a mammography procedure, a high x- ray tube load and corresponding kV value desirably allows the use of shorter exposure time thus minimizing the possibility of patient movement and ensuring adequate penetration of large or dense breasts.

#### **2.8.5 Compression**

Compression is done to reduce the thickness of the breast to enable the uniform penetration by the x-rays. Though compression of the breast during a procedure is noted to be uncomfortable for some women especially those with sensitive breast, it has some merits which include:

- Spreading the breast tissue out, making pathologic conditions or suspicious lesions easier to detect.
- Decreasing exposure times, consequently minimizing radiation dose to patient.

- Immobilizing the breast and removing blurring of the image caused by patient movement and
- Bringing the breast closer to the image plane, minimizes image magnification, and reduces focal spot blur [6, 9].

### **2.8.6 Position of Breast**

The positioning of the breast on the image receptor determines the amount of the breast tissue to appear in the image with particular attention to the region of interest (ROI) especially for diagnostic mammography. The positioning of the breast has revealed to be linked to the sensitivity of cancer detection [54]. If the patient or the breast is not well positioned, some part of the patient's body might appear on the final image and might require a repeat of the procedure resulting in more radiation dose to the patient.

For mammography equipment that uses the AEC, radiation from the x-ray unit passes through the breast and incident on the detectors of the automatic exposure control to terminate the exposure when the amount of radiation is optimum. However when the breast is not well positioned over the detectors, the detectors may receive the radiation directly from the x-ray tube leading to early termination of the exposure, and hence a poor image, which can call for the repeat of the procedure leading to more radiation dose to the patient.

### **2.8.7 Breast Thickness**

The anatomy and size of the human breast varies from one woman to the other thus the bigger or thicker the breast the bigger the area for radiation to be applied. Increased

radiation will also be needed to cover the area as well as adequately penetrate the tissues to produce an image good enough for diagnosis. Overincreasing the exposure will lead to the increased radiation dose to the patient. It is therefore very essential to select the appropriate kV to match the thickness, density and size of the breast so that the patient is not unduly exposed. Likewise, patient with smaller breast should be imaged appropriately with the right tube voltage, since there is the tendency to under or overexpose such patient. The use of the AEC is therefore recommended for the selection of the exposure factors.

### **2.8.8 Anti Scatter Grid**

The scatter grid is made up of high characteristic rations lamellae that takes up scattered radiation and is normally fitted between the image receptor and the detector. It may be movable or fixed and its function is to reduce the scatter to primary radiation ratio or to reduce the amount of scattered radiation that reaches the image receptor and detector by absorption [9, 55].

When radiation interacts with an object such as the breast it is transmitted, absorbed in the object or reflect/scatter in all direction. The transmitted radiation is known as the primary beam and is primarily responsible for the formation of the image on the film. Though some are absorbed in the body, the rest gets to the film. On the other hand radiation that reflects back in all direction is known as scattered radiation and basically contributes to the increase of patient dose. When such scattered radiation reaches the image receptor and detector, it leads to the formation of poor images reducing contrast and increasing noise. High level of scattered radiation can cause the early termination of the exposure when incident on the detector particularly when the automatic exposure

control system is being used for the procedure. In the process of absorbing the scattered radiation by the grid, the primary radiation is also absorbed. Due to the low energies used in mammography procedures, significant amount of primary radiation is absorbed during an exposure and to compensate for and improve image quality, more of the primary radiation has to be produced leading to increase dose to patient. In order to reduce more of the primary radiation being absorbed and hence increased patient dose, the grid should be designed to have a high transmittance of the primary radiation [11].

### **2.8.9 Magnification**

Magnification is achieved by increasing the distance between the breast and the image receptor while decreasing its distance to the x-ray tube during a procedure. This is done to afford the imaging of very small areas of the breast which otherwise cannot be visualized with the standard view especially during diagnostic mammography. Since mammography needs quality interpretation, some parts of the breast need to be magnified to reveal by diagnosis some critical areas. Radiation dose to patients increases during magnification because the breast is very close to the x-ray tube and there is minimum image blurring. Also during performing magnification procedure, the grid which is supposed to absorb the scattered radiation is removed, allowing scattered radiation to get to the patient thus increasing patient radiation dose.

### **2.9 Mammography Dosimetry**

There is a small but non-negligible risk of developing cancer associated with the use of x-rays for diagnostic purposes. No amount of radiation dose is risk free regardless of how

small the dose is. Though low energy x-rays are used during mammography procedures, dose to the breast needs to be assessed while ensuring that the basic principle of justification and optimization are applied. Assessing the dose delivered to the breast helps to evaluate the performance of the imaging system and also estimates the risk of patients undergoing mammography procedures.

### **2.9.1 Mean Glandular Dose (MGD)**

Due to the nature of the breast which comprises the adipose and glandular tissues, the latter is noted to be more susceptible to radiation. The inception of breast cancer normally starts from the glandular tissue within the breast [56]. Due to this, the assessment of the amount of radiation dose delivered to the glandular tissues or the breast is used to estimate the risk of patients undergoing mammography for breast cancer. The mean glandular dose (MGD) is the approved dosimetric quantity by organizations like the International Commission on Radiological Protection (ICRP), the Netherlands Commission on Radiation Dosimetry and the United States National Council on Radiation Protection and Measurements. The dosimetric quantity has been adopted by other organizations such as the European Commission and American College of Radiology and used in their protocols [12].

Assessing dose to the breast is an essential component of a quality control programme which must be implemented in every facility performing mammography procedures as well as other procedures or activities involving the use of radiation. And in accordance with the radiation protection principle, exposures must be kept as low as reasonable achievable [18]. The mean glandular dose depends on the tube voltage, breast thickness and composition. It is also affected by half value layer (HVL) and x-ray target material. It

cannot be measured directly but can be calculated from measured entrance surface air kerma (ESAK) using a standard breast phantom or a patient and other conversion factors [3, 12].

The American College of Radiology (ACR) and the Food and Drug Administration (FDA) recommends that the mean glandular dose for a standard breast should be less than 3.0 mGy (0.3 rads) per view [25, 53]. The National Health Service Breast Screening Programme (NHSBSP) in the United Kingdom (UK) and International Atomic Energy Agency (IAEA) has 2.0 mGy or less as the limiting mean glandular dose per view [25].

A research work done to estimate the mean glandular dose of women in the Ashanti Region of Ghana established that the estimated mean glandular doses were within the recommended value of 1- 3 mGy [57]. Results from other research work have also been carried out to estimate the mean glandular dose and found to be within the recommended standards [23, 58].

### **2.10 Quality Management System (QMS)**

The early detection of breast cancer relies partly on the radiologist's ability to perceive slight changes in the image that are only detectable with high quality imaging. The accurate detection of breast cancer is also dependent on the system that is used to make the diagnosis and produce the image [59]. Therefore small changes in technique or processing factors and procedures such as breast position and tube voltage or tube load can have a significant effect on the quality of image and radiation dose delivered to the breast. In applying the general principles of radiation protection to medical diagnostic radiology each procedure using x-rays must be justified and optimized. For diagnostic

radiology, including mammography, optimization means that the radiation exposure of the patient should be kept as low as is reasonably achievable (ALARA), but compatible with the image quality necessary for an adequate and accurate diagnosis [7].

To produce mammograms at the lowest doses consistent with high quality, it is necessary that careful consideration be given to well trained and experience personnel (radiographer, radiologist), selection of appropriate technique factors for exposures, accurate patient (breast) positioning, equipment in good working order and appropriate viewing conditions. These can be achieved through the establishment of an effective quality management system which must be implemented, assessed and continuously improved.

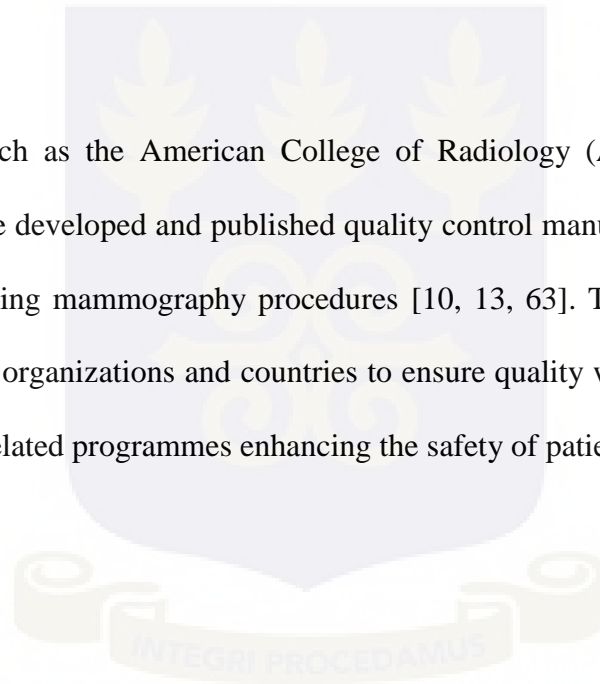
A quality management system(QMS) is a set of co-ordinated activities executed by management of a facility such as establishing policies and objectives to direct and control the organization or facility in order to continually improve the effectiveness and efficiency of its performance [60, 61, 62]. It comprises quality assurance, quality control and quality management, which is the system that manages the quality.

Quality assurance (QA) is a management tool which, through the development of policies and the establishment of review procedures, aims to ensure that every x-ray examination is necessary and appropriate to the medical problem. It includes patient dose evaluation, quality control of the x-ray system, documented policies, training and continuing education of staff, clinical audit and procedures for remedial actions. Quality control (QC) on the other hand is the technical part of quality assurance that deals with the

instrumentation and equipment used by the radiographers of a facility. It deals with techniques used in the monitoring and maintenance of the technical elements of the systems that can affect the quality within mammography program.

Quality management comprises activities and functions undertaken by management in the determination of quality policy and its successful implementation through ways including quality assurance, quality control and quality control. It also focuses on the means to successfully attain quality products and services as per the quality policy of the organization.

Organizations such as the American College of Radiology (ACR) and the European Commission have developed and published quality control manuals and requirements for facilities performing mammography procedures [10, 13, 63]. These manuals have been adopted by other organizations and countries to ensure quality within the mammography procedures and related programmes enhancing the safety of patient.



## CHAPTER THREE

### MATERIALS AND METHOD

#### 3.0 Introduction

This chapter outlines materials and methods used for the research work and measurements performed on the various mammography equipment. Details and the administration of designed questionnaires used are outlined likewise the procedures used for the assessment of the performance of the AEC and some selected quality control tests.

#### 3.1 Materials

Materials and equipment used for the study include Mammography machine(s) (Figure 3.1), Questionnaires, Leeds TORMAS Breast equivalent phantom (made up of a semi-circular test plate of 22 cm diameter, approximately 1 cm thick and an attenuator stack of acrylic plates) (Figure 3.3), AGFA Mamoray HDR (High Dynamic Range) and AGFA Mamoray (High Dynamic Screen) and High purity Aluminium absorbers (purity level of 99.9 %) of varying thicknesses (mm). The rest are a Tape measure, electrometer (Radcal Model 1015) and Ionization Chamber (Radcal Model 10X5-6) calibrated at the Secondary Standard Dosimetry Laboratory at Radiation Protection Institute (RPI) of the Ghana Atomic Energy Commission and a densitometer (Pehamed Model no: Densonorm 21i Version 2.47 SC) ( Figure 3.2).



Figure 3.1 A Mammography Machine



Figure 3.2 A Densitometer

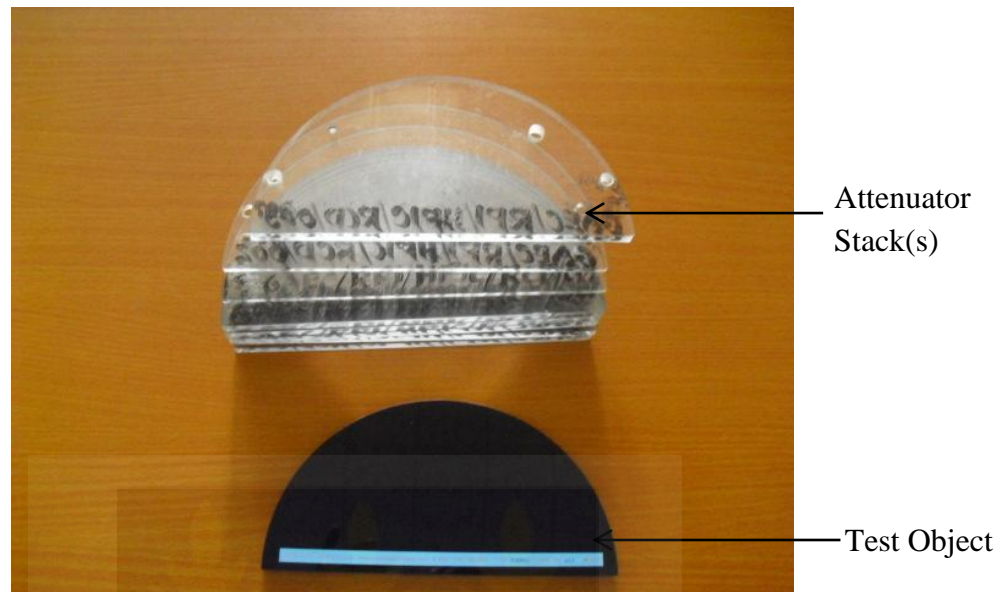


Figure 3.3 A Mammography Phantom (Leeds TOMAS Breast Phantom)

### 3.2 Method

The study was carried out in four selected facilities performing mammography procedures within the Greater Accra Region of Ghana. Four mammography equipment in the selected facilities were examined. The status and effectiveness of quality management systems in place and being implemented by the managements of the various mammography facilities with reference to international standards were assessed by means of a questionnaire.

Mammography equipment of two of the selected facilities uses the automatic exposure control system (AEC) during procedures whiles the other two mammography equipment do not.

For mammography equipment that operate with the AEC during procedures, the performance of the automatic exposure control (AEC) system was evaluated by

conducting quality control tests including the short term reproducibility test, thickness and tube voltage compensation tests. Tube voltage and tube load readings from the tests were recorded. The optical densities of images/mammograms obtained from these tests were also measured with a densitometer and compared to internationally acceptable standards.

The quality of images and patient dose were also assessed by conducting the system spatial resolution test, entrance surface air kerma (ESAK) and half value layer (HVL) tests. These tests were applicable to all selected mammography machines operating with the AEC and those operating without the AEC system. The estimated half value layer (HVL) and entrance surface air kerma (ESAK) were subsequently used to estimate the mean glandular dose (MGD).

### **3.2.1 Questionnaire Design and Administration**

A comprehensive questionnaire (Appendix I) was designed and administered to the radiographers and managers or supervisors of the selected mammography facilities. The questionnaire was used as a medium to assess the quality management system including quality control in place and being implemented by managements of these facilities as part of their responsibility to ensure that excellent radiological services are provided to patients including improving the optimization of protection of patients and staff.

Information requested from the radiographers on human resource management included their educational qualification, training, skills and working experience. The other information were on opportunities for further studies for staff and the identification of additional or continuing training by management of the facility for its staff.

Details on the type of mammography machine, the type and the commencement date of mammography procedures by the respective facilities and whether acceptance and commissioning tests of equipment was done before being used for clinical purposes were requested.

Information on the use and type of the automatic exposure control system, target and filter combination used during procedures, patient dose monitoring, confidentiality of patient's information, protective measures for patient against radiation during procedures and type of film and screen used for imaging were also requested.

Details on quality control procedures requested included the type and frequency of quality control tests performed by the radiographer(s) or engineer(s), the availability and use of quality control manual which outlines the various tests procedures, equipment to be used for the tests and their frequencies as well as documentation of tests results.

Requested information from the managers/supervisors on quality management system included documentation of policy on quality, description of management systems, accountabilities and levels of authority, procedures and instructions, patient and staff details and quality control tests result. Responsibilities of management including establishment of quality policy and objectives and measures taken by management to monitor, analysis, audit and improve processes and procedures through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review so as to ensure patients needs as well as regulatory requirements are fulfilled were requested. Other responsibilities of management requested include resources available for the implementation of quality management

system and whether a quality management committee is in place to monitor and review the quality management system periodically.

### 3.2.2 Quality Control Measurement

#### 3.2.2.1 Short Term Reproducibility Test

To assess the image stability that is the reproducibility of the AEC over a short period of time, the short term reproducibility test was performed. The test was conducted on mammography machines that use the automatic exposure control system during procedures.

The short term reproducibility test was executed by positioning a 4.5 cm PMMA phantom on the breast support, with its chest wall edge aligned with the chest wall margin of the breast support. The compression paddle was lowered until it made enough contact with the phantom. The ionization chamber was placed on the compression plate with its sensitive part positioned in the path of the x-ray beam.

Exposure factors used clinically for procedures were selected and ten exposure readings were measured consecutively. The exposure factors (target, filter, kV and mAs) used for each exposure and readings were recorded in the data collection form.

Using equation 3.1, the deviation of each value of the tube load and exposure readings from the ten exposures and the measured mAs were calculated from the computed mean value. The maximum deviation was recorded in the data collection form.

$$Deviation = \left( \frac{Value}{Mean Value} - 1 \right) \times 100\% \quad (3.1)$$

The value obtained was checked for compliance with the limiting value which indicates that the deviations from the mean value of exposures must be  $< \pm 5\%$  while the desirable value should be  $< \pm 2\%$  [25, 64].

### **3.2.2.2 Thickness Compensation Test**

The thickness compensation test was performed to assess that the automatic exposure control image stability for different phantom thicknesses. This was to check whether the AEC system compensates for different phantom (breast) thicknesses by producing images with optical densities within the target optical density for all the different phantom thicknesses.

To complete the test, a loaded cassette was placed in the bucky of the mammography machine after which a 2.0 cm breast phantom was positioned on the breast support, with the phantom's chest wall edge aligned with the chest wall margin of the breast support and laterally centred. The compression paddle was lowered until it made enough contact with the phantom. Using the markings on the compression plate it was ensured that the breast phantom completely covered all three AEC regions.

The phantom was exposed with technique factors automatically selected for that phantom thickness. The exposure factors were recorded in the data collection form and the exposed film was processed and labelled.

The same procedure was repeated for the other phantom thicknesses (4.0 cm and 6.0 cm). The exposed films were processed and their optical densities at 4.0 cm from the chest wall edge at three lateral locations of the processed films were measured with the densitometer.

The measured optical densities for the respective phantom thicknesses and the corresponding exposure factors (filter, target, kV and mAs) used during the exposures were recorded in the data collection form.

The measured average optical densities were checked for compliance with the acceptance criteria for each thickness of achievable and acceptable optical density of  $OD_{\text{target}} \pm 0.15$  and  $OD = OD_{\text{target}} \pm 0.2$  respectively [17, 25, 62].

### 3.2.2.3 Voltage Compensation Test

The voltage compensation test was performed to assess the automatic exposure control image stability at different tube voltages (kV) and that the AEC system compensates for different tube voltage values by producing optical density within the target optical density.

To complete the test, a loaded cassette was placed in the bucky of the mammography machine after which a 4.5 cm PMMA phantom was positioned on the breast support, with the phantom's chest wall edge aligned with the chest wall margin of the breast support and laterally centred.

Using the markings on the compression plate it was ensured that the PMMA phantom completely covered all three AEC regions. The compression paddle was lowered until it made enough contact with the phantom.

The PMMA phantom was exposed at a tube voltage of 26 kV. The corresponding exposure factors were recorded in the data collection form. The exposed film was processed and labeled.

The same procedure was repeated for the other tube voltages (28 kV and 30 kV). The exposed films were processed and their optical densities at 4.0 cm were measured from the chest wall edge at three lateral locations of the processed films with the densitometer. The measured optical densities for the respective voltage and the corresponding exposure factors (filter, target, kV and mAs) used during the exposures were recorded in the data collection form.

The measured average optical densities were checked for compliance with the acceptance criteria for each thickness of achievable and acceptable optical density of  $OD_{\text{target}} \pm 0.15$  and  $OD_{\text{target}} \pm 0.2$  respectively [17, 19, 62].

#### **3.2.2.4 Spatial Resolution Test**

The spatial resolution test to determine the image quality was checked and this was done by placing a loaded cassette in the bucky. The test object which contains the resolution pattern up to 20 line pairs per mm (lp/mm) was placed on top of PMMA plates (3.5 cm) which added up to a total thickness of 4.5 cm. The phantom was placed on the breast support perpendicular to the anode – cathode direction.

In the case of mammography machine that does not use the AEC, exposure factors (kV, mAs, target and filter) used clinically for such object (phantom) thickness were selected for the exposure. The film was exposed and the exposure factors were recorded in the data collection form. The same procedure was repeated with the test object placed parallel to the anode – cathode direction.

The exposed films were processed and labelled after which the number of line groups that could be clearly viewed were counted starting from the line that was most easily distinguished.

The obtained number of line groups was checked for compliance with the tolerance criteria of achievable  $>15$  lp/mm and acceptable:  $>11$  lp/mm respectively in both directions [17, 25, 62].

### **3.2.2.5 Half Value Layer (HVL)**

In order to ascertain that the total filtration of the x-ray beam is within acceptable standards, the half value layer of the x-ray beam from the various mammography machines were estimated using high purity aluminium absorbers of varying thicknesses (mm).

This was done by placing the ionization chamber on the breast support with the sensitive part of the chamber completely in the radiation field of the x-ray tube. The compression plate was placed half way between the x-ray tube and the breast support. An initial exposure was done with no aluminium absorber on the compression plate. The exposure reading on the electrometer (radcal) and exposure factors used for the exposure were recorded on the data collection form. Two other exposures were taken with the same exposure factors and the average of the exposure readings was calculated.

An aluminium absorber of thickness 0.1 mm was placed on the compression plate with its total area in the radiation beam as well as over the sensitive part of the ionization

chamber. Using the same exposure factors, three exposures were made and the average of the readings from the three exposures was calculated. Depending on the exposure readings additional aluminium absorbers of varying thickness were added until the average exposure reading was less than half the reading without aluminium absorber.

The absorbers were removed and the exposure without the aluminium absorber was repeated. The readings from the exposures (Appendix III) were recorded in the data collection form.

The half value layer (HVL) was calculated using equation 3.2

$$\text{HVL} = \frac{t_1 \cdot \ln \left[ \frac{2M_1}{M_0} \right] - t_2 \cdot \ln \left[ \frac{2M_2}{M_0} \right]}{\ln \left[ \frac{M_1}{M_2} \right]} \quad (3.2)$$

Where;

$M_0$ : Exposure reading without an added aluminium filter

$M_1$ : exposure reading that is just greater than half the reading without aluminium filter ( $M_0/2$ ) and the corresponding aluminium thickness,  $t_1$  (mm)

$M_2$ : exposure reading that is just less than half the reading without aluminium filter ( $M_0/2$ ) and corresponding aluminium thickness,  $t_2$  (mm) (17, 25)

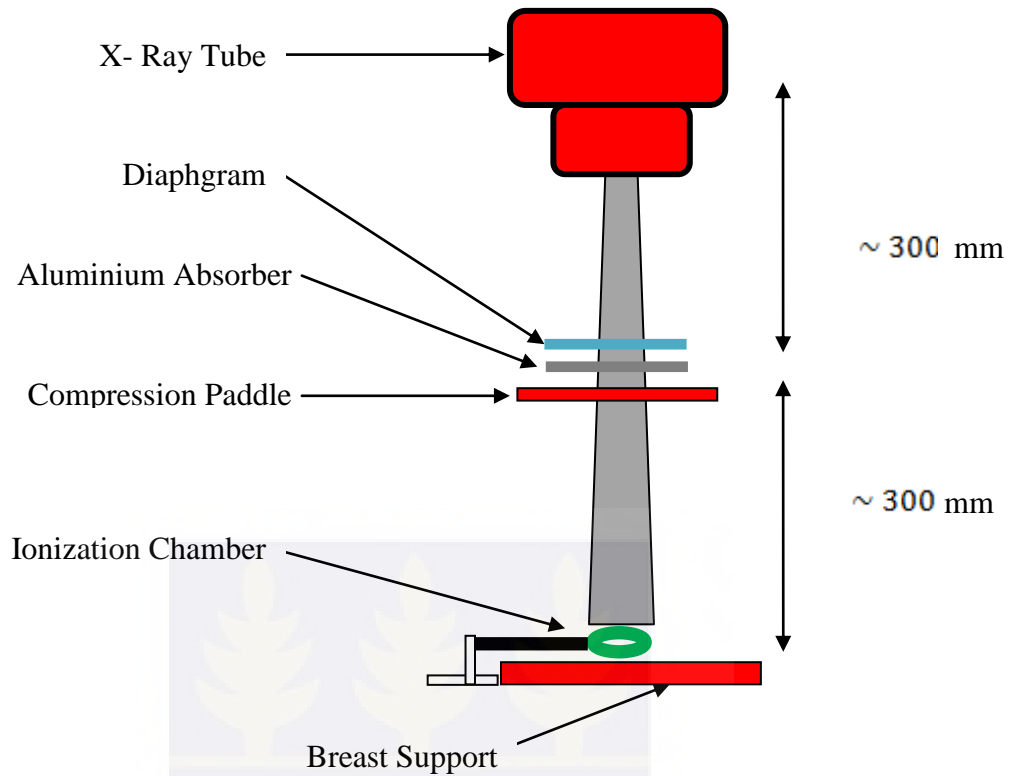


Figure 3.4 Half Value Layer (HVL) Measurement Setup

### 3.2.2.6 Film Reject Analysis

The number and causes for rejected mammograms were assessed. This was done by recording in the data collection form (Appendix II) the total number of exposed and processed films and the total number of rejected films collected during the period of study. The films were sorted out into the factors or causes leading to their rejection. The overall reject rate was calculated as the quotient of the total number of rejected films and the total number of films exposed or used during the study period expressed as a percentage, i.e. equation 3.3.

$$\text{Overall Reject Rate} = \frac{\text{Total No of Rejected Films}}{\text{Total Films Used}} \times 100\% \quad (3.3)$$

To determine the reject rate per category per facility, the number of rejects per category is divided by the total number of rejected films i.e. equation 3.4

$$\text{Reject Rate Per Category} = \frac{\text{Total Rejects per Category}}{\text{Total Rejects for All Categories}} \times 100\% \quad (3.4)$$

The film rejection rate was verified for compliance with the achievable and acceptable level of < 3 % and < 8 % respectively [19, 62].

### **3.2.2.7 Entrance Surface Air Kerma (ESAK)**

The entrance surface air kerma was determined using a phantom (4.5 cm PMMA), an electrometer (radiation monitor) and ionization chamber.

The phantom was placed on the breast support and the compression paddle was lowered until it made enough contact with the phantom. The ionization chamber was placed on the compression paddle in the field of the radiation beam. Using clinically used exposure factors, (5) five exposures were performed at different tube voltages and corresponding tube load values (mAs). The exposure readings and used exposure factors were recorded on the data collection form.

The exposure readings and the corresponding tube voltage (kV) parameters were used to plot an exponential graph for each facility (Appendix IV).

From the graph the entrance surface air kerma was calculated using the generated equation curve for each facility.

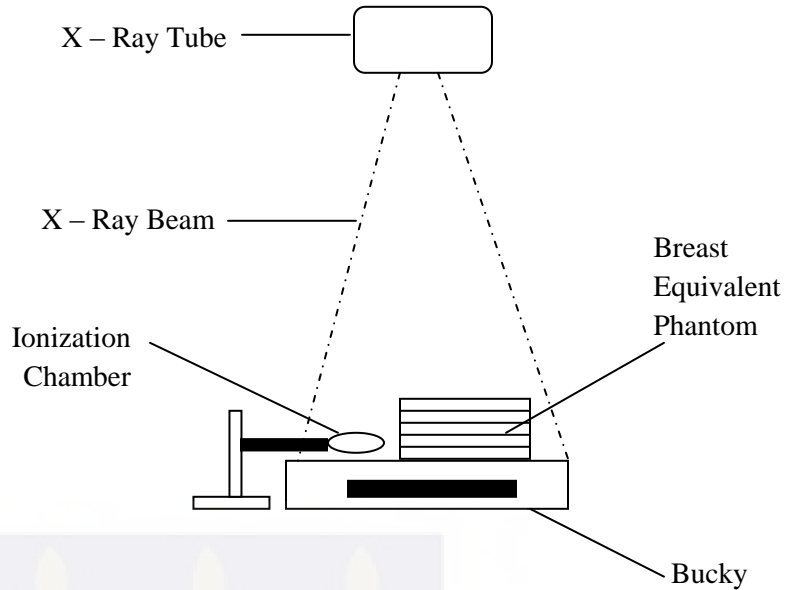


Figure 3.5: Setup for Measuring air kerma at the entrance of the standard phantom (23 , 65)

### 3.2.2.8 Mean Glandular Dose (MGD)

The mean glandular dose for a standard breast was determined. Using the estimated entrance surface air kerma and the relevant conversion coefficients, the mean glandular dose was calculated using equation 3.5.

$$\text{MGD (mGy)} = K_{gs} \quad (3.5)$$

Where;

$K_{air}$  = entrance air kerma at the surface of the 45 mm thickness of PMMA, measured without backscatter

$g$  = factor that converts the entrance air kerma to the mean glandular dose for the 53 mm thick standard breast

$c$  = conversion factor which allows for the glandularity of the 53 mm thick standard breast;

$s$  = factor which gives a correction that depends on the target filter combination [17, 25, 62].

## CHAPTER FOUR

### RESULTS AND DISCUSSIONS

#### 4.0 Introduction

This chapter presents the assessment of quality management system levels in the selected facilities based on the analysis of the responses on the questionnaires from the radiographers and supervisors. Results and analysis of the results from the various tests are discussed.

#### 4.1 Results from Questionnaire

The study was performed in four selected mammography facilities within the Greater Accra Region of Ghana. Though there are eight (8) facilities performing mammography procedures within Greater Accra Region. The studies could not be performed at four of the facilities because management did not permit the study to be carried out at their facilities while some mammography equipment of some facilities were broken down during the study period.

It was observed that two of the selected facilities (A and B) operator's use the automatic exposure control (AEC) system during procedures while the other two facilities (C and D) the operators do not use the AEC during procedures but rather select exposure factors manually.

The mammography facilities used for the study are all private facilities owned by individuals and organizations. They have been authorized to perform diagnostic mammography procedures by the Radiation Protection Board (RPB) of the Ghana Atomic Energy Commission (GAEC).

All selected facilities have one mammography equipment installed and perform both diagnostic and screening mammography procedures. Facilities A, B, C and D began performing mammography procedures since 2010, 2009, 2004 and 2011 respectively. Facilities A, C and D have resident radiographers who perform the exposures and resident radiologists who examine mammograms of patients and give appropriate diagnosis in a form of a report. According to the radiographers in the case of self referred women or asymptomatic women, (i.e. women who based on their own decision visits the facility for screening purposes) they are briefed on the findings from the examination and advised accordingly. When abnormalities are detected, patients or women are referred to a medical centre or hospital or a doctor for further examination and diagnosis to verify if the abnormalities are malignant or cancerous or otherwise. Patients referred to the facility by medical officers are given the reports addressed to the respective medical officer for further diagnosis and appropriate treatment based on the findings from the examination.

Facility B do not have a resident radiologist nor a resident radiographer but have a visiting radiographer who occasionally visit the centre to perform procedures when there are patients who need mammograms.

For all the facilities, and as a rule, acceptance and commissioning tests are performed after the installation of the mammography equipment before they are used for clinical services. An acceptance test is performed to verify that the purchased equipment operate safely and to specification. Similarly the commissioning test is performed during the acceptance test and it is used to establish baseline levels of optimum performance of the equipment. In the case of mammography, optimum exposure settings based on conditions

and features such as different breast sizes and thickness are noted during the commissioning test. These established baseline levels such as target optical density serves as guidelines and are subsequently used for quality assurance measurements. The levels are also used to ensure and maintain the optimum performance of the equipment throughout its use for providing clinical services or procedures. All the facilities concluded that acceptance tests were performed after the installation of the equipment before being used for clinical service but had no documentation (copies of the tests) to confirm that the tests were done. They also had no information as to whether the commissioning tests were performed to establish the baseline levels.

All the units providing radiography services including the mammography units of the selected facilities are managed by managers/ supervisors who have no formal training in radiography. A summary of characteristics of the various mammography equipment tested during the period of study are presented in Table 4.1.

**Table 4.1 Characteristics of the mammography equipment of selected mammography facilities used for the study**

Facility	Manufacturing Date	Installation Date	Type of Mammography Procedures	Type of Films used	Operation Mode
A	2009	2010	Screening & Diagnostic	Sony	AEC
B	1994	2008	Screening & Diagnostic	Agfa & Fuji	AEC
C	2002	2003	Screening & Diagnostic	Agfa & Fuji	Manual
D	2010	2011	Screening & Diagnostic	Agfa & Fuji	Manual

As required for every mammography facility, management must develop and effectively implement a quality management system including establishing and documenting policies, instructions and procedures related to quality, patient safety and protection and quality control programme. It was observed that facilities A and C have a documented quality policy and procedure relating to policy and patients protection, safety and privacy. Patients, staff and regulatory authority have access to these documents. Facilities B and D have no documented quality policy or procedures. Facilities A, C and D stated that they have the description of functional responsibilities, accountabilities and levels of authority within the facilities documented as well as a description of the processes and supporting information explaining how work is to be carried out and recorded.

Patient's confidentiality is very important in the medical field and as such medical service providers such as the mammography facilities must ensure that patients' information and details remain personal. To ensure this, diagnostic reports from radiologists in facilities A, C and D are sealed and addressed to the medical officer who requested for the examination. For self referred women who visit the facility for screening examination, radiologists explain the details of the diagnosis report and advise them based on the findings. In all the facilities procedures are performed behind closed doors.

It was observed that patient doses are not monitored by all the facilities and as such patients are not informed about the dose they receive during a procedure. Similarly radiographers and management have no idea about the dose delivered to the patients undergoing examination. Since patient dose monitoring is not done there is no established

diagnostic reference level to ascertain if patients' doses are above or within suitable levels. These levels are expected to be within the levels for standard procedures when best practices regarding diagnostic and technical performance are applied. In one of the facilities (Facility A) it was observed that there was no personnel monitoring in place. Though exposure levels in mammography are low it is essential that management of every facility ensure its staff (radiographers) doses are monitored.

The production of quality images is essential in mammography procedures which can translate into the provision of adequate diagnosis and minimizing the occurrence of repeats. To ensure the production of quality images, radiographers of all the facilities stated that during procedures they ensure there is enough compression of the breast to reduce motion, good positioning of the breast and patient and the selection of appropriate exposure factors in the case of those operating in the manual mode. Also when patients are booking appointment for examination at the various facilities they are informed by the radiographers to avoid using roll-on deodorant on the day of the examination because the applied roll-on deodorant can appear on the final image as artifacts decreasing the quality of the image. This may result in the repeat of the procedure. The radiographers further stated that patients are enlightened about the procedure, especially for first timers and the essence of cooperating with radiographers such as being still during the procedure. Also patients are informed to notify the radiographers when they feel uncomfortable or pain so as to help produce a good image and reduce the occurrence of repeat of procedure due to poor image.

To effectively implement a quality management system, management must exhibit its commitment in terms of its responsibility such as establishing quality objectives and

making resources available for the smooth implementation of the programme. Management of some of the facilities A, B and C have made some resources available to that effect and also improve communication between patients, staff and management thus addressing issues related to improving quality management such as addressing patients requirements and complaints .

It is vital during radiography practices that procedures and activities affecting the quality delivery of patient care and safety, effective usage of resources and the provision of optimum clinical services are documented and evaluated or audited by comparing them to good radiography practices and procedures. These can be achieved through effective clinical auditing by internal or external auditors. All the facilities do not have documented procedures for conducting internal audits, reporting results and maintaining audit records and as such do not evaluate or audit procedures and activities. And as a result corrective actions could be overdue which could lead to poor delivery of clinical services.

Film reject analysis is conducted to identify causes of rejected films and from the results the causes or reasons for rejection can be addressed to improve the facilities operation and performance. In all the facilities visited or used for the study, film reject analysis is not performed as required. Due to this, causes of film rejects are not appropriately addressed and documented to identify ways to minimize patient exposure. The reasons for film rejection are subjective and therefore vary from facility to facility. Though film reject analysis is not carried out as required, radiographers of all the facilities explained that during exposure, measures such as correct positioning, selection of appropriate

exposure factors and adequate compression of the breast are ensured to prevent poor images.

Fuji and Afga films are the most used film types by the facilities surveyed and they are kept in the dark rooms under appropriate temperature condition to prevent elements such as light and high temperatures from reducing the quality of the films

All radiographers in the respective facilities have had training and formal education in radiography with the lowest and highest education level being Diploma in radiography and Bachelor of Science (BSc.) degree in radiography respectively, making them fulfill the standards/requirements for performing mammography procedures. Through annual human resource programmes conducted by management of all the facilities appropriate records of educational, training, experience and skills of staff are maintained.

Continuous training and education for radiographers in the form of theoretical and practical training are essential to help improve their performance such as breast positioning technique, keeping them abreast with current developments in optimizing procedures and radiation protection of patients and persons involved in radiography services. It was noted that management of facilities A and C in order to ensure that quality standards are maintained and improved do identify additional and continuous education for its staff. There are also opportunities for further education for its staff. For every facility providing radiological services, staff like radiographers must receive such education and training.

To ensure that mammography and related equipment such as processors used for procedures are in good working condition and performs at a constant high quality

standard so that images produced are of good quality for diagnosis, every mammography facility must perform quality control tests regularly. Results from these tests must be documented and used as reference for future works such as maintenance as well as fulfilling regulatory requirements. To this effect, radiographers should understand the requirement of quality control and should be familiar with necessary techniques and knowledge of recording, monitoring, evaluation and the appropriate corrective actions whenever required. All the facilities under this study have no documented quality control responsibilities for radiographers and medical physicist. Since they do not have the expertise and equipment to perform the quality control tests, facilities A and C have assigned equipment maintenance, quality control responsibilities and documentation to the (company) engineers who installed the mammography equipment. For this reason the two facilities have no records of the quality control tests which are carried out every six month by the engineers. Facilities B and D on the other hand neither performed nor record the quality control tests and maintenance works, but rather repair works are carried out on the equipment by the engineers who installed the equipment when they develop faults. Three of the facilities (A, C and D) have a quality control manual or protocol while facility B did not have.

The use of exposure chart aids in minimizing exposure to patients by providing the appropriate exposure factors based on the characteristics of a particular breast such as size and thickness to be imaged. The exposure chart must be posted within the room where the mammography machine is fitted at a point that can be easily accessed by the radiographer(s). It was observed that the radiographer of Facility D use her discretion to select the exposure factors and cassette size based on the thickness and size of the breast

whiles the radiographer of Facility C uses the exposure charts in selecting exposure factors for examination.

#### **4.2 Quality Control Measurements**

The least alteration in the performance of the mammography equipment can have an impact on the quality of images produced and on radiation to patients. Quality control measurements are performed to ascertain that the mammography equipment is performing at a stable, high quality level.

Mammography equipments used for this study were in good working condition with no electrical or mechanical faults detected. The performance of the AEC systems was satisfactory in some tests such as compensation of thickness and tube voltage variations. All the facilities did not have a target optical density since the commissioning tests were not performed to establish baseline levels such as the target optical density. International organizations such as the International Atomic Energy Agency (IAEA) recommend the establishment of a target optical density which should be based on factors such as type of films used, and be within the range of 1.5 -1.9 optical density OD (17).

Results of the quality control measurements of the mammography equipment surveyed during the study period are presented in Tables 4.2 to 4.12.

##### **4.2.1 Short Term Reproducibility**

From Table 4.2 the highest deviation of the mean values of tube load and exposure were found to be 8.59 % and 9.85 % respectively. Facility A recorded 8.59 % and 9.85 % as the highest deviation values from the mean of tube load (mAs) and exposure respectively which were above the acceptable criteria of  $\pm 5$  %. For facility B, deviation of the mean

value of exposure of 1.65 % was lower than the acceptable limit. Also the deviation of tube load of 5.54 % being the highest mAs deviation was higher by 0.54 % above the acceptable limit.

**Table 4.2 Results of short term reproducibility measurements of the selected equipment that uses the AEC during the survey**

Facility	Target/ Filter	Mean Exposure (mGy)	Max. Dev. From Mean Exposure (%)	Mean mAs	Max. Deviation from mAs (%)
A	Mo/Mo	3.86	9.85	45.86	8.59
B	Mo/Mo	2.49	1.65	28.92	5.54

#### 4.2.2 Thickness Compensation

The ability of the automatic exposure control system to compensate for different breast thicknesses was evaluated using different phantom thicknesses.

The facilities whose operators use the AEC during procedures were found to compensate for different thicknesses of phantom by producing comparable measured optical densities (OD) of which some are within the recommended standard target optical density 1.5 -1.9 OD(17).

From Table 4.3 measured optical densities of mammograms produced from mammography equipment of facility B were within the range of the recommended target optical density (OD) for each phantom thickness. Facility A recorded the highest optical density of 2.00 OD for both 2.0 cm and 4.0 cm phantom thicknesses while facility B recorded the least optical density of 1.77 OD for the 4.0 cm phantom thickness. The highest and lowest optical densities differ by a factor of 0.95 and 1.07 respectively as

against reference to the highest limit of the target optical density of 1.9 OD. Difference in the optical densities can be attributed to factors such as the film type. Since facilities met the approved optical density it implies that image quality of the mammograms is optimum that implying the images are detailed enough or show the features of the breast thus providing the necessary information for interpretation and subsequent diagnosis.

Structures of the breast such as the glandular tissues are clearly exposed at optical densities between 1.5 - 1.9 OD [17]. Moreover the glandular tissue produces the lowest optical densities on a mammogram and if optical densities are too low or too high, the likelihood of finding low contrast lesions in the glandular tissues is reduced.

**Table 4.3 Results of thickness compensation measurements of the selected mammography equipment that uses the AEC during examination.**

Facility	Exposure Mode	Target/ Filter	Optical density (OD) for different Phantom Thicknesses (cm)		
			2.0 cm	4.0 cm	6.0 cm
A	AEC	Mo/Mo	2.00 ± 0.02	2.00 ± 0.03	1.90 ± 0.03
B	AEC	Mo/Mo	1.97 ± 0.02	1.77 ± 0.05	1.81 ± 0.01

#### 4.2.3 Voltage Compensation

The tube voltage determines the penetration strength of the x-ray beam through an object (the breast) and an essential factor to consider when selecting exposure factors for a radiological practice based on the size and density of object to be imaged. The AEC compensates for tube voltage variations by adapting the energy of the x-rays to the attenuation of the breast or to the glandular tissue of the breast. The AEC systems of the

selected mammography equipment were found to compensate for different tube voltages by producing optical densities (OD) within the recommended range though some of the measured optical densities were slightly higher than the maximum limit of the target optical density.

From Table 4.4 measured optical densities of 1.80 OD , 1.82 OD and 1.90 OD at tube voltages of 26 kV, 30 kV and 28 kV respectively fell within the recommended target optical density with facilities A and B recording the highest and lowest optical densities of 2.03 OD and 1.80 OD respectively for the tube voltage of 26 kV.

The highest optical density was higher by 0.13 above the highest limit of the recommended value of 1.9 OD. Likewise by a value of 0.1 the lowest optical density was lower than the standard optical density. Differences in the measured optical densities between the facilities could be attributed to factors such as film type and processing condition.

Though some of the measured optical densities are within the limits and some slightly above the recommend target optical density, diagnosis from mammograms of such optical densities are elaborated enough since essential details within the breast can be clearly seen. Non compliance to the criteria may imply that some very useful details of a mammogram may not be visible enough, thus limiting quality interpretation and diagnosis. It is important that optical densities are sufficiently high to aid the detection of small invasive cancers [25].

**Table 4.4 Results of voltage compensation measurements of the selected mammography equipment that uses the AEC during examination.**

Facility	Exposure Mode	Target/ Filter	Optical Densities (OD) for Different Tube Voltage (kV)		
			26 kV	28 kV	30 kV
A	AEC	Mo/Mo	2.03± 0.01	1.97± 0.02	1.82± 0.02
B	AEC	Mo/Mo	1.80± 0.02	1.90± 0.01	1.94± 0.02

#### 4.2.4 Spatial Resolution

Spatial resolution is one of the factors that is used to determine the quality of an image. The ability to detect small discrete details on an image is determined by the spatial resolution at a contrast either high or low. The spatial resolution of images produced by mammography equipment of the selected facilities was assessed in the two anode-cathode directions. Results shown in Table 4.5 indicate that in the parallel anode-cathode direction, all facilities recorded a resolution of 15 line pairs per millimeter (lp/mm) while in the perpendicular anode – cathode direction, facility B recorded the least resolution of 14 line pairs per millimeter (lp/mm). The spatial resolution obtained for all the equipment selected for the study complied with the acceptable criteria of >11 line pairs per millimeter (lp/mm) (17).

The spatial resolution of the equipment tested indicates that images of structures on the mammogram are distinguishable. And non compliance to the standards implies images on the mammograms may not be distinct enough to clearly distinguish the breast anatomy.

In comparing the quality of images produced from an equipment using the AEC system and those that do not use the AEC system during procedures, indicates that images from either equipment type have a good image in terms of the contrast resolution and are adequate for revealing details such as calcifications, shapes and numbers. Since both exposure modes are producing such good images, and in order to enhance the ALARA principle, the mammography equipment that operates with the AEC system during procedures is recommended for performing procedures.

**Table 4.5 Results of spatial resolution measurements of mammography equipment of the selected mammography facilities.**

Facility	Target/ Filter	Parallel Anode-Cathode Direction			Perpendicular Anode-Cathode Direction		
		kV	mAs	Resolution (lp/mm)	kV	mAs	Resolution (lp/mm)
A	Mo/Mo	29	19.7	15	26	14.7	15
B	Mo/Mo	30	18.6	14	30	18.4	15
C	Mo/Mo	28	71.0	15	28	71.0	15
D	Mo/Rh	28	36.0	15	28	36.0	16

#### 4.2.5 Half Value Layer (HVL)

The ability of the x-ray beam produced by the selected mammography equipment to penetrate the breast (phantom) was assessed by measuring the half value layer or the beam quality. Based on the acceptable criteria the half value layer,

$HVL \geq kVp/100 + 0.03$ , where kVp is the tube voltage value (17). At 28 kV, facilities B and D recorded the highest and lowest half value layer figures of 0.35 mm Al and 0.29 mm Al respectively. Facilities A and C also registered half value layers of 0.30 mm Al and 0.32 mm Al. Half value layer figures of 0.30 mm Al and 0.29 mm Al were lower by 0.01 and 0.02 respectively from the limiting values of 0.31 mm Al ( $kVp/100 + 0.03$ ) at 28 kV. Estimated half value layers from facilities A and D were within the acceptable range. From the results (Table 4.6) the mammography equipment of the selected facilities showed sufficient filtration of the x-ray beam for optimized patient dose and good quality image production.

**Table 4.6 Results of Half Value Layer (HVL) measurements of mammography equipment of selected mammography facilities.**

Facility	Exposure Mode	Tube Voltage (kVp)	Tube Load (mAs)	Half Value Layer (mm Al)
A	AEC	28	70	0.30
B	AEC	28	50	0.35
C	Manual	28	71	0.32
D	Manual	28	36	0.29

#### 4.2.6 Mean Glandular Dose (MGD)

The mean glandular dose assessment in mammography is very critical since the breast glandular tissue is considered as one of the most radiosensitive tissues. The International

Atomic Energy Agency (IAEA) recommends that for mammography procedures, the mean glandular dose should be  $< 2.0$  mGy and at most  $< 2.5$  mGy per view for a breast phantom thickness of 4.5 cm (17). Likewise as per the standards of the American College of Radiology (ACR), the mean glandular dose should be  $< 3.0$  mGy (62). From the results (Table 4.7) estimated mean glandular dose at different tube voltages (kV) per the ACR standard were lower than the recommended value of  $< 3.0$  mGy (ACR) and the acceptable value of  $< 2.5$  mGy (IAEA). Facility A recorded the highest values of entrance surface air kerma and mean glandular dose of 13.12 mGy and 2.4 mGy respectively at 32 kV. Facility B and C recorded the least mean glandular dose of 0.8 mGy at 26 kV and entrance surface air kerma of 5.07 mGy and 4.88 mGy respectively.

**Table 4.7 Results of Entrance Surface Air Kerma (ESAK) measurements of mammography equipment of selected mammography facilities.**

Facility	Exposure Mode	Target/Filter	Entrance Surface Air Kerma (ESAK)(mGy) at different Tube Voltages (kV)			
			26 kV	28 kV	30 kV	32 kV
A	AEC	Mo/Mo	4.22	6.16	8.99	13.12
B	AEC	Mo/Mo	5.07	6.86	9.28	12.55
C	Manual	Mo/Mo	4.88	6.40	8.40	11.02
D	Manual	Mo/Rh	3.56	4.79	6.44	8.66

**Table 4.8 Results of Mean Glandular Dose (MGD) measurements of mammography equipment of selected mammography facilities using 4.5 cm phantom thickness.**

Facility	Target/ Filter	Mean Glandular Dose (MGD) (mGy)			
		26 kV	28 kV	30 kV	32 kV
A	Mo/Mo	0.6	1.0	1.2	2.4
B	Mo/Mo	0.8	1.3	1.8	2.2
C	Mo/Mo	0.8	1.1	1.6	2.0
D	Mo/Rh	0.6	1.1	1.2	1.7

At 28 kV, the mean glandular dose for facility B was lower than that of IAEA (2.0 mGy) and ACR (3.0 mGy) by the highest factor of 1.5 (Table 4.9) and 2.3 (Table 4.10) respectively compared to other facilities. Facility A recorded a mean glandular dose which was lower than the acceptable standard of 2.0 mGy (IAEA) and 3.0 mGy (ACR) by the least factors of 2 and 3 respectively. Facilities that recorded the highest and least mean glandular doses differ by a factor of 1.3.

From the results, it is noted that facilities performing mammography procedures are operating within the recommended radiation dose levels which is vital to patient safety likewise for radiographers. It is important that patients undergoing diagnostic or screening procedures are not overexposed while other factors required to ensure optimum image quality are seriously considered during an examination or procedure.

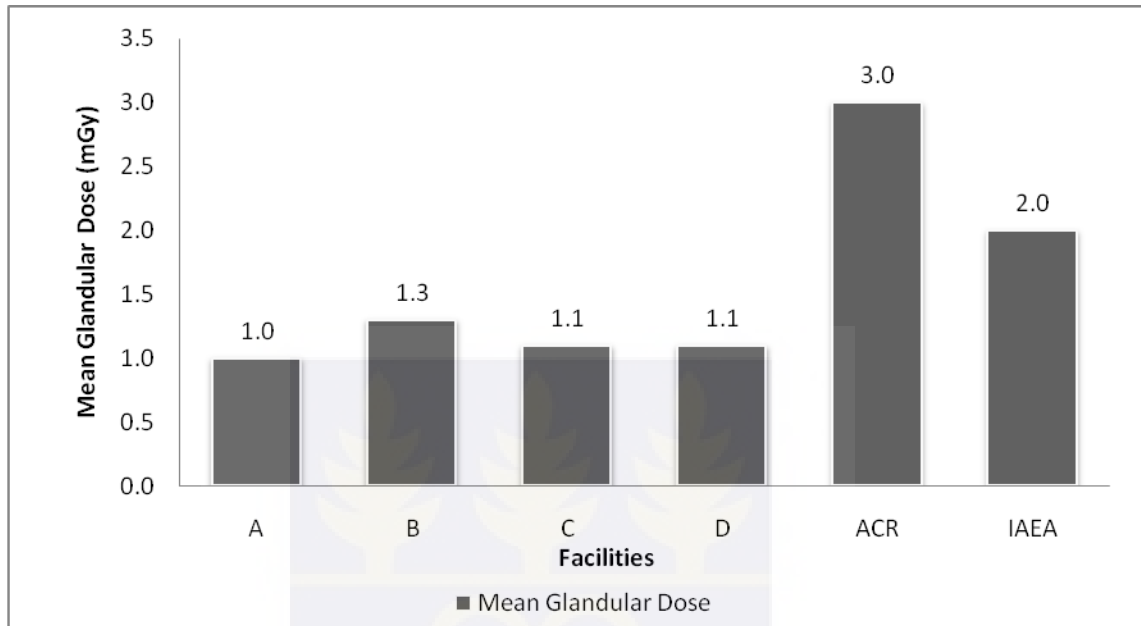
**Table 4.9 Comparison of estimated mean glandular dose (MGD) per (4.5 cm) PMMA thickness and 28 kV of selected mammography facilities with International Atomic Energy Commission (IAEA) standard.**

Facility	Mean Glandular Dose (MGD)(mGy)	IAEA/ Facility's MGD
A	1.0	2.0
B	1.3	1.5
C	1.1	1.8
D	1.1	1.8
IAEA	2.0	1.0

**Table 4.10 Comparison of estimated mean glandular dose (MGD) per (4.5 cm) PMMA thickness and 28 kV of selected mammography facilities with American College of Radiology (ACR) standard.**

Facility	Mean Glandular Dose (MGD) (mGy)	ACR/ Facility's MGD
A	1.0	3.0
B	1.3	2.3
C	1.1	2.7
D	1.1	1.7
ACR	3.0	1.0

**Figure 4.1 Comparison of estimated Mean Glandular Dose (MGD) of selected mammography facilities with those of American College of Radiology (ACR) and International Atomic Energy Agency (IAEA).**



#### 4.2.7 Film Reject Analysis

Film reject analysis was carried out for a period of 5 months (20 weeks). From the results of the reject analysis as shown in Table 4.11 the lowest and the highest total percentage reject recorded were 1.27% and 9.21% for facilities D and B respectively. Film reject implies avoidable exposure to patients due to repeat of the procedure and economical loss in terms of finance and time to the respective facility since new resources such as new films are needed to repeat the procedure. The percentage of rejects should guide the facility especially the radiographers to institute measures to eliminate causes of film reject.

**Table 4.11 Film reject rate as a percentage of total numbers of films of selected mammography facilities.**

Facility	Total № of Films used	Total № of films rejected	Rejected Rate %
A	90	6	6.67
B	76	7	9.21
C	800	18	2.25
D	864	11	1.27

**Table 4.12 Causes/Reasons for rejection of films for selected mammography facilities**

Facility	Reasons for Rejection (%)				
	Patient Motion	Positioning	Too Dark Films	Too Light Films	Others
A	50.00	50.00	0.00	0.00	0.00
B	28.57	0.00	14.29	28.57	28.57
C	11.11	11.11	38.89	22.22	16.67
D	9.10	18.18	27.27	27.27	18.18

Film rejects due to films being too dark or too light could be attributed to processing problems such as underprocessing or overprocessing. It could also be attributed to

equipment (processor) fault that needs to be repaired. Inappropriate selection of exposure factors by radiographers could also affect the appearance of the processed films being too dark or too light. The exposure chart used during procedures may need to be updated if poor appearance is linked to the selection of exposure factors. In the category of too dark films, facility C recorded the highest figure of 38.89 % while facility B recorded a figure of 28.57 % for the too light films category. It was realized that the processor of facility C was old compared to the others and occasionally breaks down and could be a factor for producing too dark and too light films. Inappropriate selection of exposure factors could also be a reason for such observations.

Correct patient (breast) positioning with particular reference to the region of interest in the instance of diagnostic mammography and patient motion are factors that must be given critical attention in mammography procedures. It plays an important role in obtaining optimum images good for diagnosis while minimizing patient dose. Film rejects as a result of positioning accounted for 50 %, 11.11 % and 18.18 % for facilities A, C and D respectively (Table 4.12). The high film reject rate as a result of poor positioning could be ascribed to inadequate or lack of continuous training of radiographers or a slight movement of the breast by the patient just before the exposure. Radiographers briefing patients on the implication of movement during procedures before the actual procedure can help reduce rejects due to movement of patients.

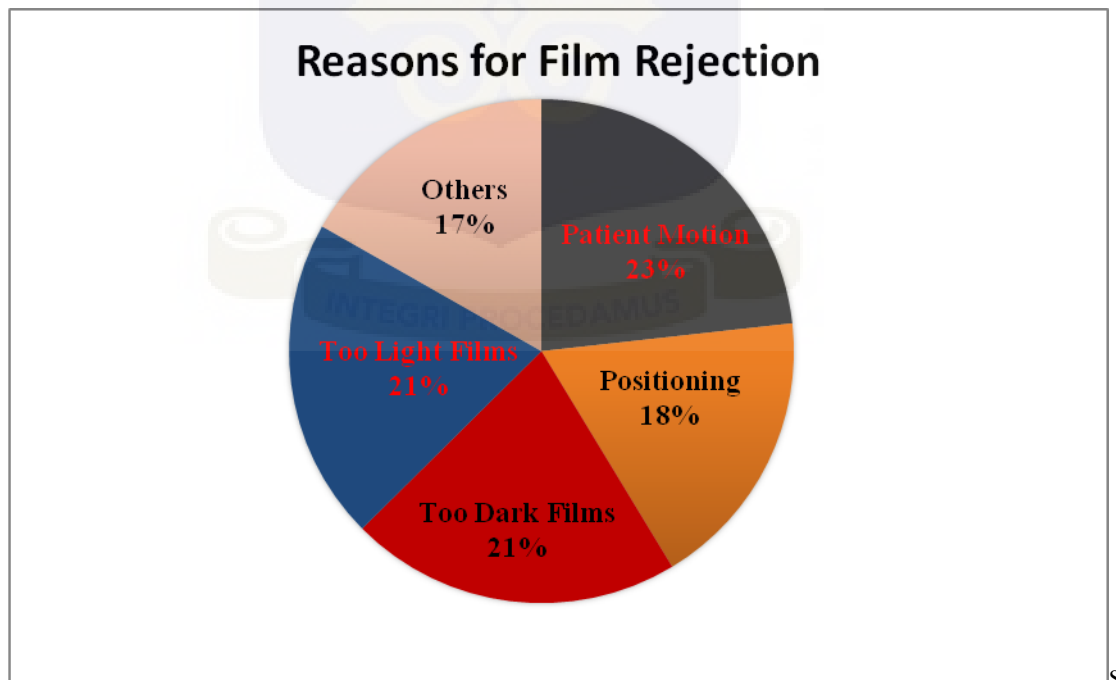
Patient motion as shown in figure 4.2 accounted for the highest reasons of film rejects from all the facilities. From Table 4.12, facility A recorded the highest film rejects of 50 % due to patient motion while facility C recorded the least value of 9.10 %.

Appearance of artifacts on the processed films which could be attributed to poor storage and handling of films as well as rollers marks from the processor and darkroom mix-ups

of films during processing which can result in incorrect labelling of films accounted for the ‘others’ category of film rejects in facilities B, C and D.

From the overall film rejects results (Tables 4.11 and Table 4.12), film rejects for facilities using AEC during procedures compared to facilities not using the AEC are comparable but vary from facility to facility based on factors such the experience of the radiographer and condition of the processors. The latter may record rejects due to poor selection of exposure factors.

With an effectively implemented quality management system in place, a greater part of film rejects which are due to human error and deficiencies as well as inadequate maintenance could be reduced to the minimum. Regular training of radiographers can also help improve their proficiency and skills in patient positioning thus help reduce retakes.



**Figure 4.2 Chart showing overall reasons for film rejection in all of the selected mammography facilities.**

## CHAPTER FIVE

### CONCLUSION AND RECOMMENDATION

This chapter presents final conclusion from the study and some recommendations for managements of mammography facilities and the regulatory authority towards the optimization of mammography procedures.

#### 5.1 Conclusion

Analysis of the information obtained from the questionnaire administered to the mammography facilities assessed revealed that they did not meet quality management system performance requirements. The deficient areas include; lack of appropriate education and training programmes, absence of documentation of policies related to quality objectives and procedures, lack of quality control programmes, no patient dose assessment and absence of quality management committees to ensure that well documented quality management system programmes are monitored and reviewed periodically as recommended by organization such as the International Atomic Energy Agency (IAEA).

Different tests performed to evaluate the performance of the automatic exposure control (AEC) system of two mammography equipment in the study revealed that the AEC systems of mammography equipment used during procedures compensates for variation in phantom thicknesses and tube voltages by producing comparable optical densities. Most of the measured optical densities were within standard target optical density.

For system spatial resolution of mammography equipment using the AEC during procedures, facilities A and B recorded values of 15 lp/mm and 14 lp/mm respectively in the parallel anode-cathode direction while those that do not use the AEC namely facilities C and D also record of resolution value of 15 lp/mm, being all above the acceptable criteria of  $\geq 11$  lp/mm.

Facilities A, C and D recorded reject rates of 6.67 %, 2.25 % and 1.25 % respectively and were within the acceptable level  $< 8$  %. Facility B recorded the highest reject rate of 9.21 % which was 1.21 % higher than acceptable level of 8 %.

Amongst the selected facilities, facility B recorded the highest half value layer of 3.5 mm Al while facility D registered the least half value layer of 2.9 mm Al at 28 kV. The estimated half value layer values are within the recommended limits of 0.31 mm Al. This is an indication the x-ray beam qualities are acceptable for imaging.

The values of the estimated mean glandular dose demonstrated that radiation doses delivered during procedures are within the recommend Diagnostic Reference Levels (DRLs) with facilities B and A recording the highest and lowest mean glandular dose (MGD) of 1.3 mGy and 1.0 mGy respectively at a tube voltage of 28 kV for a 4.5 cm breast equivalent phantom thickness. Differences in dose levels observed could be attributed to variation in mammography equipment characteristics, type of AEC and selection of exposure factors by AEC and radiographers. It was also observed that facility D using Molybdenum/Rhodium target/filter combination recorded the lowest mean glandular dose of 1.7 mGy at 32 kV.

It is expected that findings from this study when disseminated will form the basis for management of mammography facilities to satisfactorily provide radiological services and improve their outcomes through the establishment and implementation of an effective quality management system.

## **5.2 Recommendation**

### **5.2.1 Management of Mammography Facilities**

Management of the mammography facilities studied must institute an effective quality management system which must be implemented, assessed and continually improved through review and must be in line with the quality objectives of the facility. Management must demonstrate its commitment to the establishment, implementation, assessment and continual improvement of the management system by allocating adequate resources necessary and make them available to carry out quality management activities.

Management must make sure that its staff involved in radiological activities are involved in continuous education and training on a regular basis. This can help improve their proficiencies in performing procedures.

Doses delivered to patients should be monitored to ensure patients are not overexposed. Patient dose monitoring should be done every six months and after any major maintenance and repair works.

All mammography facilities should develop exposure charts to aid in the selection of exposure factors depending on the type of mammography equipment and AEC system. These exposure charts should be updated after any major repair work has been carried out on the equipment

Lessons learned from daily operational activities should be fed back into the operating experience of the facility to improve the production of quality images good enough for diagnosis while protecting patients from overexposures.

### **5.1.2 Regulatory Authority**

The regulatory authority must ensure that management of mammography facilities establish and implement a quality management system. Also documentation of quality management system including quality assurance and quality control information such as maintenance and repair works, film reject analysis, policies, training programmes and patients and staff exposure evaluation and any implemented corrective actions are checked during inspections.

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## APPENDICES

### APPENDIX I

#### UNIVERSITY OF GHANA

#### DEPARTMENT OF NUCLEAR SAFETY AND SECURITY (NSAS) GRADUATE SCHOOL OF NUCLEAR AND ALLIED SCIENCES

#### QUESTIONNAIRE FOR OPERATORS OF MAMMOGRAPHIC EQUIPMENT AND MANAGERS/SUPERVISORS OF MAMMOGRAPHY FACILITIES

Dear Sir/Madam,

I am conducting a research on the topic **“EVALUATION OF THE PERFORMANCE OF THE AUTOMATIC EXPOSURE CONTROL SYSTEMS FOR SOME SELECTED MAMMOGRAPHY FACILITIES IN GREATER ACCRA REGION, GHANA”**.

The research seeks to investigate basically into the optimal use of the automatic exposure control systems of mammographic equipment by some mammography facilities towards the optimization of procedures and patients radiation protection.

The purpose of this questionnaire is to collect information about the facility/hospital, mammographic equipment, the operator(s) the use of the automatic exposure control systems during procedures and quality management systems of the facility (quality assurance and quality control).

I am kindly requesting you to spare some of your valuable time to complete this questionnaire.

This research work is solely towards the award of a Master of Philosophy (M.Phil) degree in Radiation Protection and **NOT** for any commercial or profit making purpose.

Thank You very much for your kindness.

Richard Amesimenu

**A. GENERAL INFORMATION**

Name of Facility.....

Location.....

Address.....

Officer(s) in Charge.....

1. How many mammographic machines do you have at the facility/hospital?

2. What is the name of the manufacturing company of the mammographic equipment(s)?

3. What is the model and type/made of the mammographic equipment(s)?

4. What is the manufacturing date of the mammographic equipment(s)?

5. When was the machine(s) installed?

6. Was an acceptance test performed during the commissioning of the equipment(s)?

Yes [ ] No [ ]

7. What category of mammography procedures are the facility licensed to perform?

(i)Diagnostic mammography [ ] (ii) Screening mammography [ ]

(iii)Both [ ]

8. What category of procedures is the facility currently performing?

- (i)Diagnostic mammography [ ] (ii) Screening mammography [ ]  
(iii)Both [ ]

9. How long has the facility being performing mammography procedures?  
.....

## **B. QUALITY MANAGEMENT SYSTEMS**

Quality Management system is a set of coordinated activities to direct and control an organization to ensure that its objectives are achieved and continually improved in an effective and efficient way. Quality control and Quality assurance are two important component of quality management system. A management system combines all elements of an organization into one coherent system to enable all of the organization's objectives to be achieved. These elements include the structure, resources and processes, personnel, equipment and organizational culture and documented policies and procedures. A well established, implemented, assessed and continually improved quality management system ensures that health, environmental, security, quality and economic and safety requirements are fulfilled. Regulatory and statutory requirements are also fulfilled.

### **Documentation**

10. Does the facility have a document on the following;

- a. Quality policy                      Yes [ ]                      No [ ]
- b. A description of the functional responsibilities, accountabilities and levels of authority.                      Yes [ ]                      No [ ]
- c. A description of the processes and supporting information that explain how work is to be carried out, reviewed, carried out, recorded, assessed and improved.

Yes [ ]                      No [ ]

11. What measures are there to ensure confidentiality of patient-related information?  
.....  
.....

12. Is there a policy in place to monitor, analyze and report, and periodically review procedures or activities that may have the potential to affect the smooth implementation of quality management system?    Yes [ ]                      No [ ]

13. Does the facility/hospital ensures that personnel have access to quality management system documentation i.e. policies; procedures; instructions etc      Yes [  ]  
No [  ]
14. Do patients have access to quality management systems related documents?  
Yes [  ]      No [  ]
15. Do regulatory authority's representatives have access to quality management systems related documents?      Yes [  ]      No [  ]

### **Management Responsibility**

16. Has management ensured the following;
- a. Establish a quality policy for the facility/hospital?      Yes [  ]      No [  ]
  - b. Establish quality objectives?      Yes [  ]      No [  ]
  - c. Made resources available for the smooth implementation of quality management systems.  
Yes [  ]      No [  ]
  - d. Patients, statutory and regulatory requirements are fulfilled. Yes [  ]      No [  ]

### **Responsibility, Authority and Communication**

17. Does the facility have a quality management committee that included representatives from all departments or levels of the facility/hospital?      Yes [  ]      No [  ]
18. Does management review the quality management systems to ensure the continuing suitability, adequacy and effectiveness? Yes [  ]      No [  ]
19. Are records of such review kept/archived and made available when necessary?  
Yes [  ]      No [  ]
20. Does management make resources available to implement and maintain the system and continually improve its effectiveness as well as enhance patient's satisfaction by meeting patient requirement?      Yes [  ]      No [  ]
21. Has management ensured that appropriate communication processes are established within the facility/hospital and that communication takes place regarding the effectiveness of the quality systems?      Yes [  ]      No [  ]

22. Are information such as the average duration for diagnostic mammography procedure and the amount of radiation received during the procedure and information regarding the possibility of pain or discomfort made known to patients? Yes [ ] No [ ]
23. Are there arrangements for patient communication related to mammography procedures information and patient's complaints?  
Yes [ ] No [ ]

### **Monitoring, Measurement, Analysis and Improvement**

24. Does the facility/hospital plan and implement monitoring, measurement, analysis and improvement of processes and procedures? Yes [ ] No [ ]

If yes, how often/frequency?  
.....

25. Does the facility/hospital have a procedure on monitoring patient's information as to whether patient's needs are fulfilled? Yes [ ] No [ ]
26. Does the facility/hospital perform internal clinical audits?  
Yes [ ] No [ ]
27. Is there a documented procedure that defines the responsibilities and requirements for planning and conducting internal audits, and for reporting results and maintaining records?  
Yes [ ] No [ ]
28. Are external auditors engaged to perform clinical audit for the facility/hospital?  
Yes [ ] No [ ]

### **Human Resource**

29. Does the facility/hospital maintain appropriate records of education, training, skills and experience of staff? Yes [ ] No [ ]
30. Are additional and continuing training needs of staff identified by the facility/hospital and met to ensure that the quality standards are maintained and improved?  
Yes [ ] No [ ]
31. Are there opportunities for further education for personnel? Yes [ ] No [ ]

32. Does the facility perform/conduct annual individual Human Resource Development?  
 Yes [  ]                      No [  ]

**Improvement**

33. Does the facility/hospital continually improve the effectiveness of the quality management systems through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review?  
 Yes [  ]                      No [  ]

**C. QUALITY CONTROL**

34. Who is/are (Radiographer, medical Physicist, Engineers) responsible for conducting and documenting quality control activities and what is their educational qualification?

Officer(s)	Educational Qualification

35. Does the facility have a quality control manual for the performing the various QC tests?  
 Yes [  ]                      No [  ]

36. Does the quality control manual indicate the following?

- a. The measuring instrument or tools to be used.    Yes [  ]                      No [  ]
- b. The operational details?    Yes [  ]                      No [  ]
- c. Which officer (Radiographer, Medical Physicist, Technologist) is required to perform the tests?    Yes [  ]                      No [  ]
- d. The qualification of person(s) required to perform the tests.    Yes [  ]                      No [  ]
- e. The recommended frequency of tests and their respective tolerance and limiting values?  
 Yes [  ]                      No [  ]

37. Do you perform quality control tests at your facility and at what frequencies?

TESTS	YES/NO	FREQUENCY
1. Reproducibility and accuracy of kVp		
2. Beam Quality Assessment-HVL		
3. Alignment of X ray field/image receptor and tube output		
4. X ray film processor (sensitometry, temperature);		
5. Measurement of optical density control setting of AEC, Thickness compensation, Voltage compensation, Reproducibility of AEC		
6. Brightness and homogeneity of viewing boxes		
7. Phantom Image Quality Evaluation		
8. Measurement of focal spot size, source-to image distance		

38. Are patient doses monitored? Yes [  ] No [  ]

If No, State reasons.

.....

.....

39. How does the facility control exposures to patients undergoing procedures?

.....

.....

40. How are patients protected from under or over exposure of patients during procedures?

.....

.....

41. When there is an overexposure to the patients, do you inform the patients?

Yes [  ] No [  ]

If yes, how do you inform them?

.....  
 .....  
 42. What is your choice of film types for procedures?

.....  
 .....  
 43. What are the reason(s) for your choice?

.....  
 .....  
 44. How are films kept at your facility?

.....  
 .....  
 45. What is the type/make of equipment used in your facility?

Equipment	Type/Make
• Screen	
• Cassette	
• Film processor	
• Anode material	
• Filtration material	

.....  
 .....  
 46. How do you ensure quality image during procedures?

.....  
 .....  
 47. Is the AEC system of the mammographic equipment utilized during procedures?

Yes [ ] No [ ]

If No, State

reasons.....

.....

.....

48. What AEC modes and target/filter combination are used and under what circumstances?

.....

.....



**APPENDIX II**

**DATA COLLECTION FORM**

**Film Reject Analysis**

Officer(s) In Charge: .....

Period of Study; From: ..... To: .....

Total number of films used during the study period: .....

<b>Causes/Reasons for Film Reject</b>	<b>N<sup>o</sup> of Films</b>
• Too Light Films	
• Too Dark Films	
• Positioning	
• Motion	
• Technical	
<b>Total N<sup>o</sup> of Rejected Films</b>	

**APPENDIX III**

**HALF VALUE LAYER (HVL) OR BEAM QUALITY MEASUREMENT**

**Table III.1** Aluminium thickness and corresponding exposure values obtained for facility A

<b>Aluminium Thickness (mm)</b>	<b>Exposure (mGy)</b>		<b>Average Exposure (mGy)</b>
0	5.087	5.104	5.096
0.1	4.595	4.595	4.595
0.2	3.648	3.657	3.653
0.3	2.964	2.947	2.956
0.5	2.122	2.105	2.114
0.6	1.754	1.754	1.754
0.7	1.482	1.465	1.474

Tube Voltage = 28 kV    Tube Load = 70 mAs

**Table III.2** Aluminium thickness and corresponding exposure values obtained for facility B

<b>Aluminium Thickness (mm)</b>	<b>Exposure (mGy)</b>		<b>Average Exposure (mGy)</b>
0	3.184	3.190	3.187
0.1	2.669	2.652	2.661
0.2	2.035	2.059	2.047
0.3	1.628	1.621	1.625
0.5	1.190	1.184	1.187
0.6	0.720	0.725	0.723

Tube Voltage = 28 kV    Tube Load = 50 mAs

**Table III.3** Aluminium thickness and corresponding exposure values obtained for facility C

<b>Aluminium Thickness (mm)</b>	<b>Exposure (mGy)</b>		<b>Average Exposure (mGy)</b>
0	5.297	5.309	5.301
0.1	4.341	4.350	4.346
0.2	3.894	3.553	3.724
0.3	3.596	3.596	3.596
0.5	2.096	2.105	2.101
0.6	1.842	1.842	1.842
0.7	1.535	1.535	1.535

Tube Voltage = 28 kV      Tube Load = 71 mAs

**Table III.4** Aluminium thickness and corresponding exposure values obtained for facility D

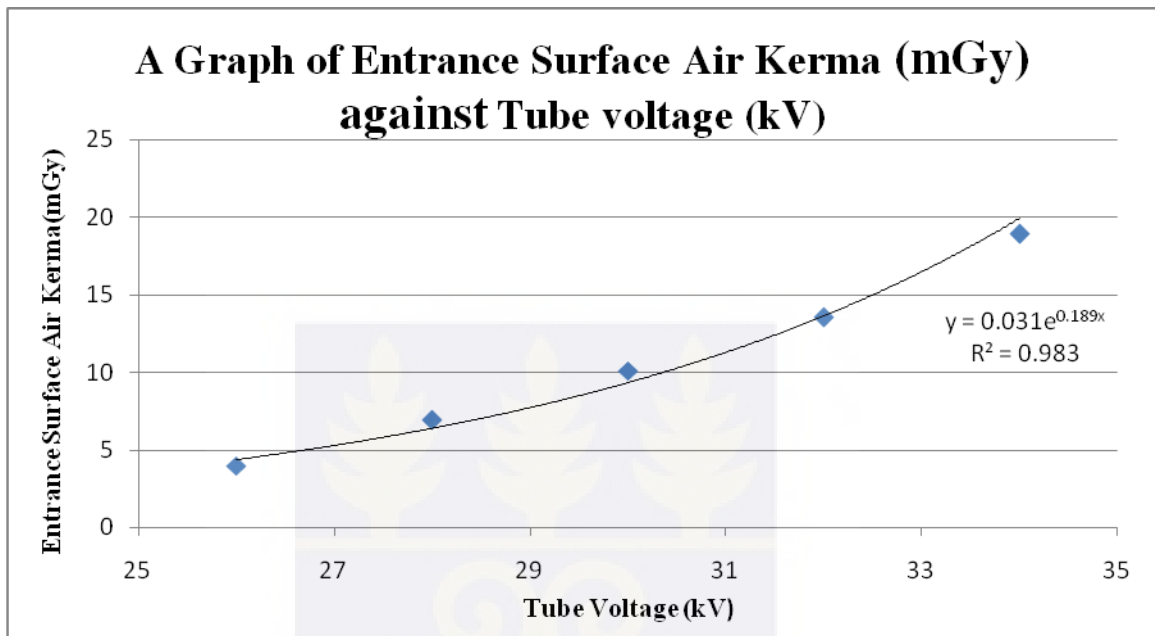
<b>Aluminium Thickness (mm)</b>	<b>Exposure (mGy)</b>		<b>Average Exposure (mGy)</b>
0	3.420	3.438	3.429
0.1	3.096	3.096	3.096
0.2	2.780	2.798	2.789
0.3	1.596	1.596	1.596
0.5	1.394	1.412	1.403
0.6	1.070	1.070	1.070
0.7	0.956	0.973	0.965
0.8	0.871	0.873	0.872

Tube Voltage = 28 kV      Tube Load = 36 mAs

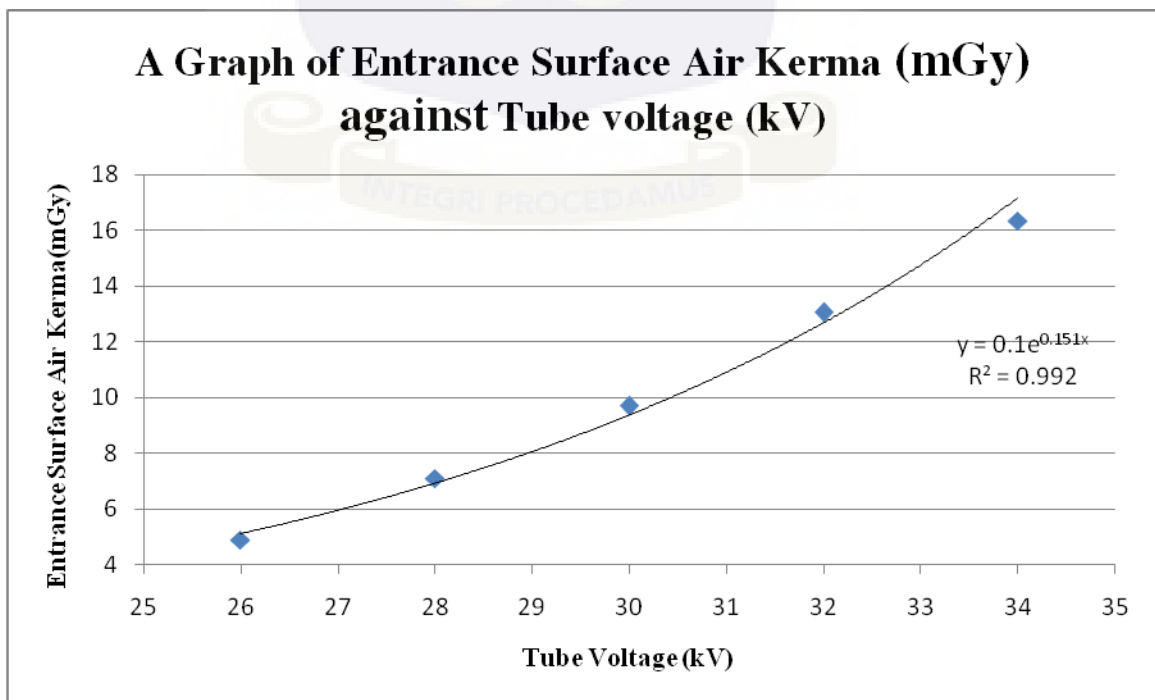
**APPENDIX IV**

**ENTRANCE SURFACE AIR KERMA (ESAK) MEASUREMENTS**

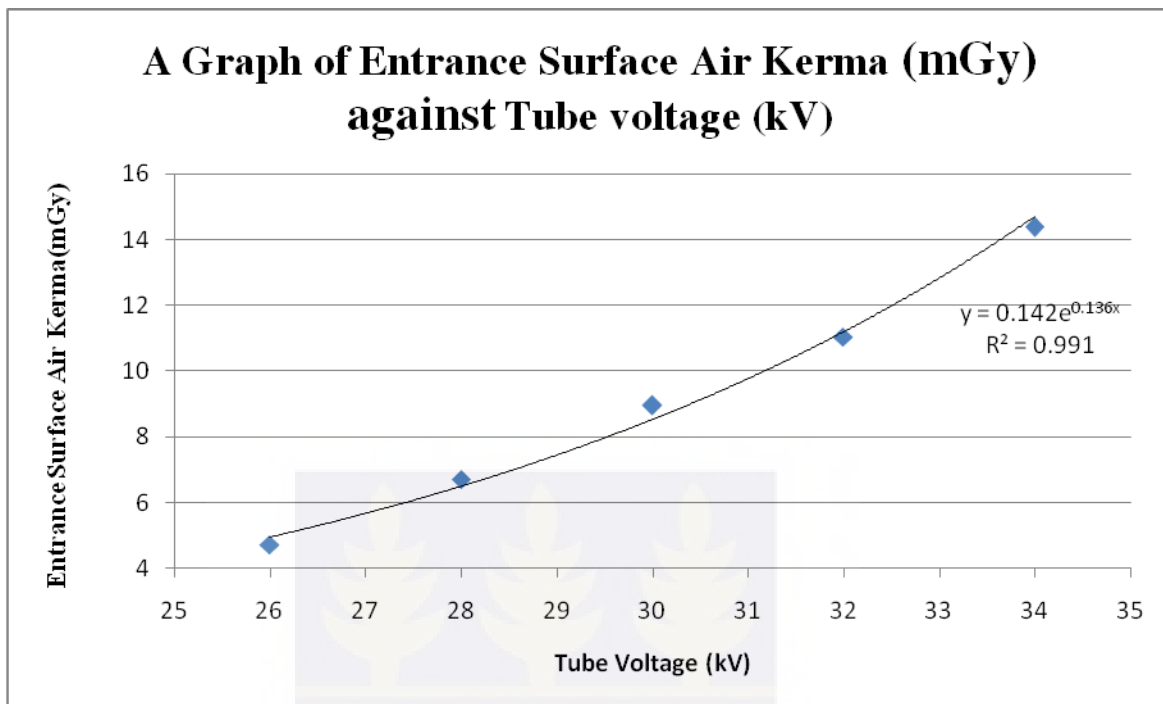
**Figure IV.1** Entrance Surface Air Kerma (ESAK) measurement for facility A



**Figure IV.2** Entrance Surface Air Kerma (ESAK) measurement curve for facility B



**Figure IV.3** Entrance Surface Air Kerma (ESAK) measurement curve for facility C



**Figure IV.4** Entrance Surface Air Kerma (ESAK) measurement curve for facility D

