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Evaluation of quality control and quality assurance programs in Egyptian X-ray Mammogram Units: Achievements and Challenges

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ABSTRACT

An effective quality assurance (QA) program in X-ray mammography units is a challenge and should be practical to harmonize practices and routine work. A standard operating protocol (SOP) must be in place to ensure that all the relevant objectives and subjective metrics of the imaging chain are operating properly. Identify the challenges and difficulties of daily practice and determine the requirements that are needed. In this study, the quality assurance (QA) in X-ray mammography was evaluated to identify and analyze the protocol currently available in hospitals according to the requirements of the Egyptian regulatory authority at the Ministry of Health. This will provide useful guidance to implement and develop an Egyptian quality assurance (QA) program in X-ray mammography units. A quality assurance program was studied and implemented at three x-ray mammography units to ensure diagnostic accuracy. The values of all the parameters undergoing measurement are compared with the limiting values given by international protocols. The parameters described have been studied and analyzed in detail since the quality control program in mammography was implemented. Such parameters as reproducibility and accuracy of kVp, half-value layer (HVL), tube output, and compression test were measured, and the results were summarized. The values obtained prove the constant and correct functioning of the equipment. The results obtained indicate that more efforts are needed to increase the management of breast cancer with improved radiological safety for patients.

1. Introduction

Mammography is currently considered the best tool for the early detection of breast lesions [1].

A medical physicist must conduct all applicable mammography equipment evaluations before using the unit to examine patients [2].

The availability of quality assurance (QA) programs is important. A daily procedure for quality control should be in place to ensure that all the imaging chain is carried out in an optimal manner [3]. Fourteen guidance documents for QA and QC in mammography published between 1991 and 2011 were identified [4, 5, 6, 7, 8, 9, 10, 11 & 12]. For Quality Assured Breast Screening and Diagnostic Services [EUREF] and the European Commission (EC), three are internationally proposed by the IAEA and ten have national or regional scope (United States of America [USA], Canada, Australia, the United Kingdom [UK], Ireland, and the Nordic countries) by governmental bodies, professionals, and/or scientific organizations [13].

Testing the X-ray generator, the alignment of the X-ray, the repeatability and accuracy of tube output exposure, the half-value layer (HVL), the AEC response versus breast thickness, tube voltage compensation, and the alignment of the compression plate [14].To implement a mammography QC/QA program, parameters should be selected depending on the available technology and resources [15]. The radiologic signs of breast cancer include mass lesions, micro-calcifications, asymmetries between images of the two breasts, and architectural distortion. To detect this sign accurately at the earliest possible opportunity, all factors influencing the acquisition, display, and interpretation of the mammogram must be optimized, and those optimum conditions must be obtained [16].

According to the American Association of Physicists in Medicine (AAPM), the medical physicist performs or supervises the technical aspects of procedures necessary to assure the safe and effective delivery of radiation because of the absence of an integrated system for assessing the quality of mammography services, which is considered the main factor in image quality and dose assessment [17]. In this work, three mammography units were evaluated according to the Ministry of Health regulatory requirements. The QC tests included voltage (kVp) accuracy, mAs, half-value layer (HVL) measurement, machine output using a Victoreen 4000+ multi-meter, compression paddle, radiation leakage measurements, and radiation survey using a survey meter.

2. Materials and method

The quality Control (Q.C) tests were obtained on three digital mammography units, which have different target combination filters (Mo, Rh, W). The technical details of the units were summarized in Table 1. kVp accuracy & repeatability, half-value layer (HVL), machine output repeatability & linearity and compression paddle calibration (force, alignment, thickness) were obtained using Victoreen 4000+ multimeter device, Slabs of Poly-methyl-methacrylate (PMMA), commonly called Perspex was used to mimic different thickness of the female breast, Aluminum sheets, measuring rule, Lawn tennis ball and bathroom scale.

2.1. kVp accuracy

The kVp accuracy was manually adjusted for different settings by gradually increasing its value from 25 to 35 kVp at constant mAs and T/F combination at the focus-to-detector distance (FDD) of 65 cm by placing the Victoreen 4000+ multimeter on the breast support [18]. The measured kVp (kVpmea) at each exposure was recorded. The parameters set were also recorded. The kVp accuracy was determined by calculating the percentage deviation of the measurements recorded using the following equation:

$$\text{Deviation } (\%) = \frac{\text{KVp nom} - \text{KVpmea}}{\text{KVpnom}} * 100 \qquad (1)$$

Where: kVp_{nom} is the selected on the machine; kVp_{mea} is the average of measured kVp value.

$$\text{Difference } (\%) = \frac{\text{Max. reading} - \text{Min. reading}}{\text{Min. readin}} * 100 \qquad (2)$$

Where, Max. reading is maximum reading of KVp measured and Min. reading is minimum reading of KVp measured

2.2. Tube out put

The X-ray tube generator's performance and filtration were used to check the production of images with an acceptable short exposure time [19]. The tube output was measured at various kVp ranging from 25 to 35 kVp at fixed tube currents of 5 mAs and 10 mAs. the output linearity was calculated using the following equation:

$$\text{L } (\%) = \frac{y1 - y2}{y1 + y2} * 100 \qquad (3)$$

Where: y1 and y2 are the output values obtained at a consecutive mAs value by dividing each average exposure (mGy) value by the corresponding mAs.

The acceptable linearity of output must be less than 10%. The average of (mGy/mAs) was calculated, and its consistency at each kVp station was checked by evaluating the coefficient of variation (COV) using the equation

$$COV = \frac{SD}{Mean} * 100 \quad (4)$$

Where: SD is the Standard Deviation calculated over measured kVp, and mean is the average of the measured kVp.

2.3. Beam quality

The Victoreen 4000+ Multimeter was placed on the center of the bucky at 65 cm FDD, and operating parameters were selected ranging from 25 to 35 kVp at constant 5 and 10 mAs setting in each filter combination, (Mo/Mo) (T/F) combination [20]. In each exposure, the HVL value was recorded and compared with its corresponding HVL range, which is calculated using the following equation:

$$HVL = \frac{X1 * \ln\frac{2Y2}{Y0} - X2 * \ln\frac{2Y1}{Y0}}{\ln\frac{Y2}{Y1}} \quad (5)$$

Where Yo is the direct exposure reading (mGy), Y1 and Y2 the exposure reading with added aluminum thickness of X1 and X2 respectively.

Verification was then made to confirm whether the total filtration of each machine was within the international standard range required by IAEA [21] using the equation:

$$\frac{kVpmea}{100} + 0.03 \leq HVLmea \leq \frac{kVpmea}{100} + C \quad (6)$$

Where: kVpmea is the measured value for the nominal kVp selected; HVLmea is the measured filtration. 0.03 is a factor that compensates for the thickness of the compression plate, and C is a factor that compensates for the anode/filter combination used (C = 0.12 for MO/MO, 0.19 for MO/Rh, 0.22 for Rh/Rh, and 0.30 for W/Rh).

2.4. Compression test

The compression paddle is an important factor to check. It is used to vary the breast thickness and reduce the breast dose [22]. So, a flat conventional weighing scale was placed on the bucky, and the X-ray tube was fixed at a cranio-caudal view. Then, the compression paddle was pushed at a maximum level toward the bucky (loaded with cassette). At that time, the magnitude of weight in kilograms (kg) was noted in each mammography unit, which was then converted into Newton's (N) using the relationship 1 kg = 9.8066 N.

3. Result

Table 1. Characteristics of mammography units

Mammogram unit	Manufacture	Target filter combination
unit1	General Electric (GE) Oct-2013	(Mo/Mo), (Mo/Rh) and (Rh/Rh)
unit 2	FujiFilm Aug-2015	W/Rh
unit 3	Siemens (mammot C) Oct-1991	Mo/Rh

3.1. kVp Accuracy

Table 2. Values of nominal kV, measured kV, tube voltage accuracy and reproducibility measured for unit 1 at 50 mAs and target filters combination Mo/Mo, Mo/Rh and Rh/Rh.

Nominal kV	Mo/Mo				Mo/Rh				Rh/Rh			
	Measured kV	Deviation (±5%)	Difference (≤5%)	COV% (≤2%)	Measured kV	Deviation (±5%)	Difference (≤5%)	COV% (≤2%)	Measured kV	Deviation (±5%)	Difference (≤5%)	COV% (≤2%)
25	25.98	-3.916	0.013	0.622	27.27	**-9.076**	2.257	1.229	28.2	**-12.81**	1.441	0.718
26	26.68	-2.624	1.651	0.829	27.63	**-6.265**	1.298	0.671	28.28	**-8.786**	2.015	1.025
27	27.55	-2.021	1.537	0.764	28.07	-3.946	0.919	0.462	28.69	**-6.267**	1.203	0.619
28	28.84	-2.980	0.672	0.377	28.52	-1.849	0.387	0.194	28.98	-3.50	0.496	0.249
29	29.77	-2.667	0.505	0.267	29.15	-0.509	0.562	0.303	29.57	-1.962	1.237	0.623
30	30.8	-2.667	0.293	0.146	29.83	0.574	0.223	0.115	29.99	0.029	0.211	0.108
31	31.86	-2.763	0.168	0.091	30.68	1.029	0.381	0.206	30.54	1.491	0.131	0.066
32	32.8	-2.50	0.132	0.067	31.55	1.406	0.127	0.066	31.23	2.392	0.299	0.164

Table 3. Values of nominal kV, measured kV, Deviation of measured kV and Difference of measured kV at 100 mAs for unit 2, 3 with target filters combination W/Rh, Mo/Mo respectively.

Nominal kV	Unit 2 (W/Rh)				Unit 3 (Mo/Mo)			
	Measured kV	Deviation (±5%)	Difference (≤5%)	COV% (≤2%)	Measured kV	Deviation (±5%)	Difference (≤5%)	COV% (≤2%)
25	----	----	----	----	25.75	-2.991	**5.091**	**2.497**
26	----	----	----	----	26.92	-3.521	1.259	0.629
27	28.46	-5.395	1.059	0.746	27.27	-1.012	0.576	0.289
28	29.01	-3.601	0.518	0.365	28.61	-2.187	1.289	0.653
29	29.61	-2.098	0.417	0.294	29.39	-1.375	0.409	0.209
30	30.24	-0.811	0.265	0.187	30.55	-1.844	1.941	0.986
31	31.09	-0.290	0.021	0.015	31.45	-1.452	1.377	0.691
32	31.99	0.005	0.344	0.243	32.12	-0.375	0.489	0.257

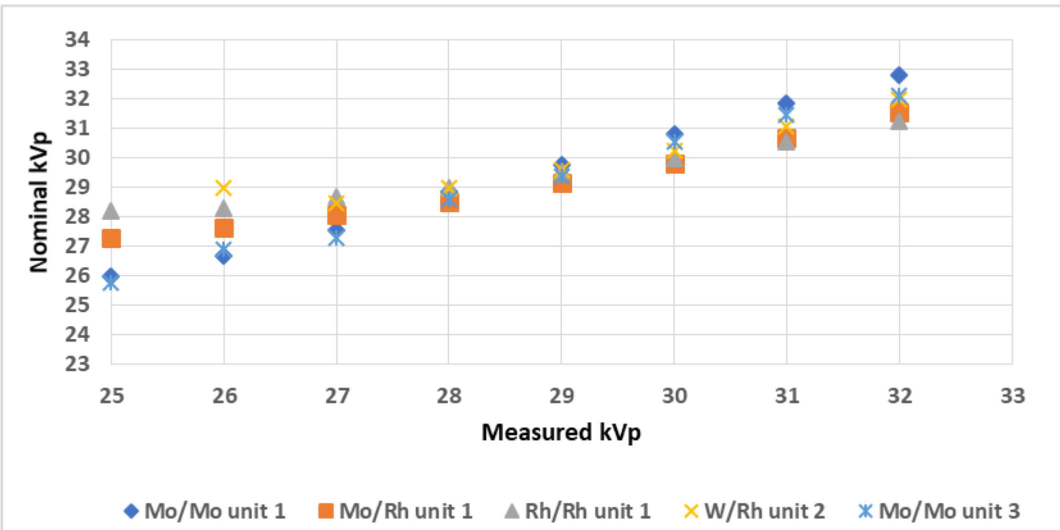

Fig. 1 Relation between nominal kVp and measured kVp at 3 units with different target filter combinations.

3.2. Half value layer (HVL)

Table 4. Values of exposure with Aluminum sheet thickness for 3 units for Mo/Mo, Mo/Rh, Rh/Rh, W/Rh anode filter combinations at 28 Kvp

28 Kvp	unit 1(at 50 mAs)						unit 2 (100 mAs)		unit 3 (100 mAs)	
	Mo/Mo		Mo/Rh		Rh/Rh		W/Rh		Mo/Mo	
Al-thickness (mm)	average exposure (mR)	transmission	average exposure (mR)	transmission	average exposure (mR)	transmission	average exposure (mR)	transmission	average exposure (mR)	Transmission %
0	1276.67	100	1027	100	898.80	100	722.925	100	1506.33	100
0.1	1017	79.66	847.37	82.50893	742.33	82.60	636.4	88.03	1200.67	79.70
0.2	832.85	65.23	711.87	69.32	590.10	65.65	510.65	70.64	984.80	65.38
0.3	683.53	53.54	594.63	57.90	523.70	58.27	411.1	56.87	816.90	54.23
0.4	565.53	44.30	504.60	49.13	446.40	49.67	376.55	52.09	671.37	44.57
0.5	-	-	-	-	-	-	337.025	46.62	-	-
Measured HVL (mmAl)	0.336		0.389		0.395		0.437		0.341	

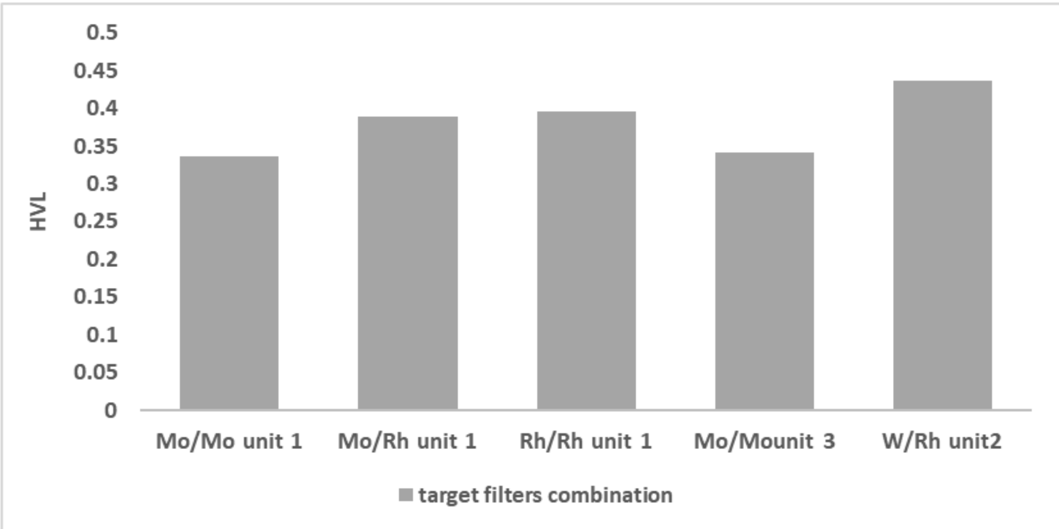

Fig. 2 Values of HVL for all units with different target filter combinations.

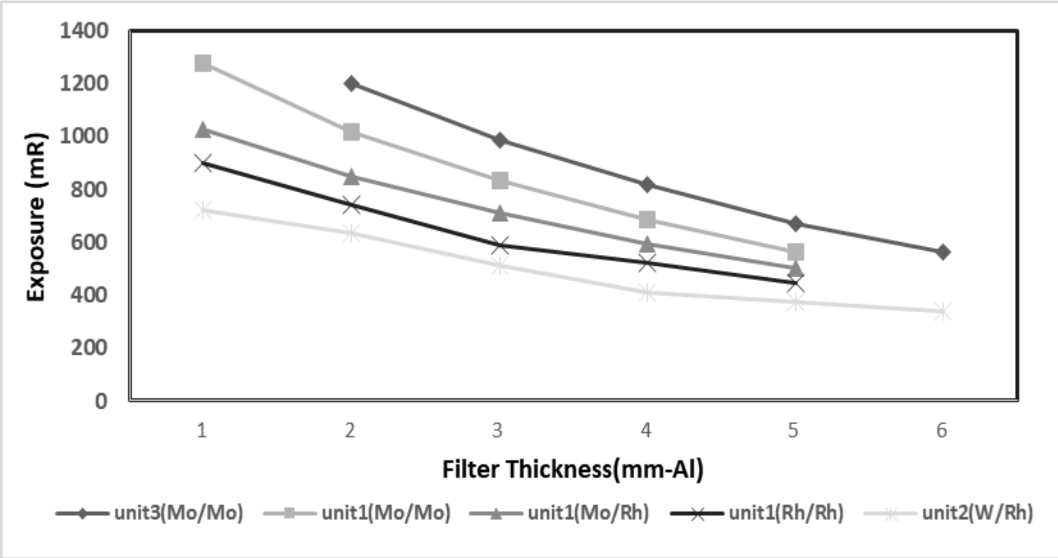

Fig. 3 Relation between Aluminum Thickness and Exposure for all units with different target filter combinations.

3.3. Tube output measurements

Table 5. Values of exposures and output with different mAs at 28 Kvp at all units with different target filter combinations

28 Kvp		mAs	Differences of exposure %	Output(µGy/mAS)	COV%
Unit 1	Mo/Mo	80	0.3913	111.8	0.1958
		100	0.1569	111.5	
		125	0.1256	111.3	
	Mo/Rh	80	0.1824	89.90	0.2749
		100	0.0969	90.10	
		125	0.1548	90.30	
	Rh/Rh	80	0.6654	78.90	0.2003
		100	0.0555	78.70	
		125	0.0888	78.70	
Unit 2	w/Rh	80	0.0261	41.80	0.6308
		100	0.2537	41.40	
		125	0.4270	41.30	
Unit 3	Mo/Mo	80	0.0013	172.9	14.865
		100	0.0013	131.7	
		125	0.0025	139.1	

Table 6. Values of tube output with range of Kvp (25:32) at unit 1 Mo/Mo, Mo/Rh, Rh/Rh, values of tube output with range of Kvp (27:32) at unit 2 and unit 3 for W/Rh, Mo/Mo anode filter

Kv	Output(µGy/mAs) 50 mAs (unit 1)			Output(µGy/mAs) 100 mAs	
	Mo/Mo	Mo/Rh	Rh/Rh	W/Rh, unit2	Mo/Mo, unit3
25	72.932	57.491	50.876	-	-
26	83.569	66.754	59.796	-	-
27	95.179	76.221	66.993	37.965	79.051
28	107.156	86.486	75.295	41.362	127.453
29	118.597	96.268	84.547	45.371	142.183
30	132.85	107.231	94.253	49.319	159.622
31	146.608	118.824	104.274	52.969	173.071
32	160.472	130.550	114.748	56.738	200.553

Table 7. Linearity of tube output at all units with different target filter combinations

output linearity	unit 1			unit 2	unit 3
	Mo/Mo	Mo/Rh	Rh/Rh	W/Rh	Mo/Mo
L1	0.1272	0.1718	0.1828	0.5081	13.5321
L2	0.0653	0.0999	0.0203	0.0676	2.7180
L3	0.1925	0.2718	0.1625	0.5757	10.8539

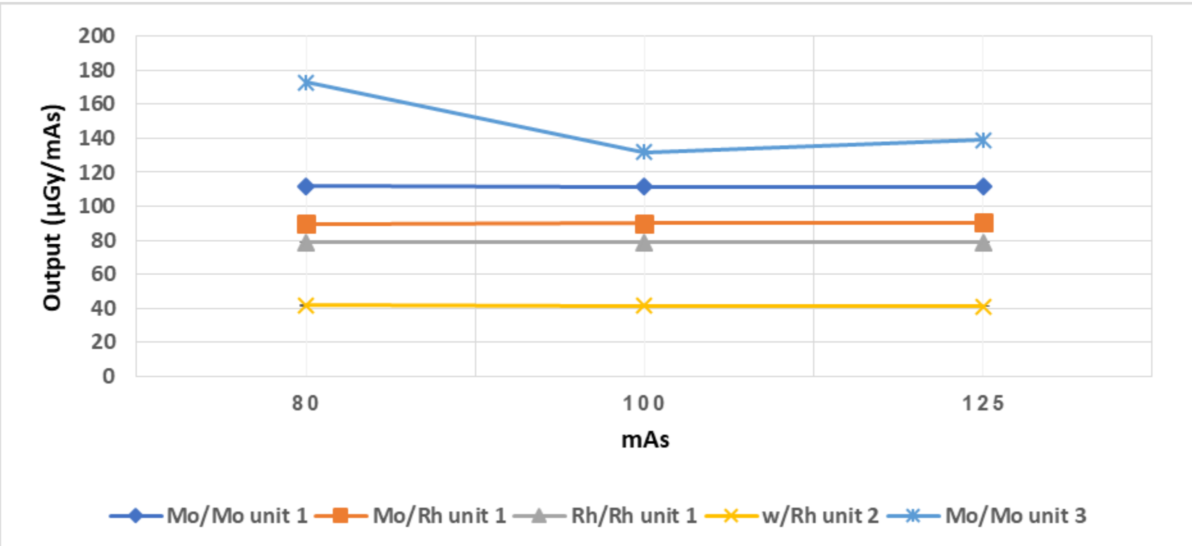

Fig. 4 Relation between tube output and three different value of mAs (80,100,125) with different target filter combinations

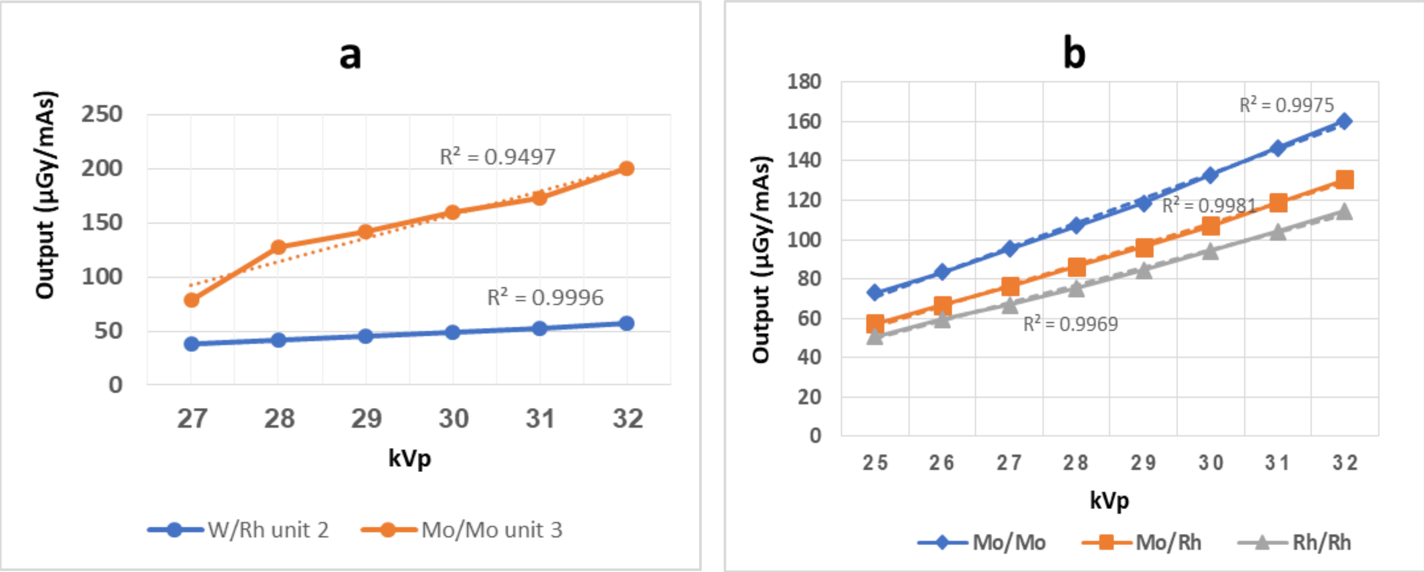

Fig. 5 (a)Tube output at range (27:32) Kvp at unit 2 (W/Rh) and unit 3 (Mo/Mo) (b) Tube output at range (25:32) Kvp at unit 1 with different target filter combinations (Mo/Mo,Mo/Rh and Rh/Rh).

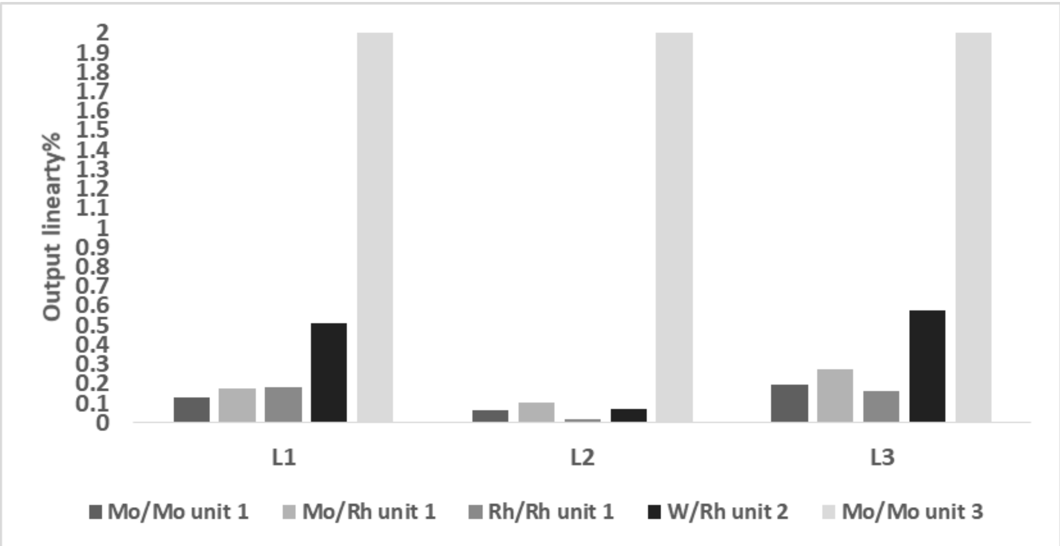

Fig. 6 Output linearity for all units with different filter combinations.

3.4 Compression tests

Table 8. Results of compression test for 3 units of mammography.

Compression tests (Acceptable range)	Results			Pass/fail
	unit 1	unit 2	unit 3	
Compression Alignment (> -5 mm , <5 mm)	1 mm	1 mm	2 mm	Pass
Compression indicator (> -5 mm , <5 mm)	3 mm	4 mm	3 mm	Pass
Compression Force (≤ 20 N)	4 N	9 N	10 N	Pass

4. Discussion

4.1. kVp Accuracy

The nominal tube voltage (kVp) used during medical examinations in mammography falls within the range (25–32 kVp) at 50 mAs for unit 1. Regarding unit 2, the nominal tube voltage (kVp) used falls within the range (27–32 kVp) at 100 mAs, while in unit 3, the nominal tube voltage (kV) used falls within the range (25–32 kV) at 100 mAs. The kVp values for each nominal tube voltage were measured using a calibrated test device and are represented in Tables 2 and 3 at different target filter combinations. The absolute percent difference between the nominal and measured kVp and its deviation was calculated using equations (1, 2).

The percentage of deviations in kVp accuracy calculated using equation 1 for all mammography units with different target filter combinations at various kVp with 50 and 100 mAs is given in Tables 2 and 3. From Table 2, it is observed that the deviation in measured kVp reaches a maximum value of -9.075% and -6.265% at 25 and 26 KVp, respectively. For target filter combinations Mo/Rh and Rh/Rh, the deviation in measured kVp reaches a maximum value of -12.809%, -8.786%, and -6.267% at 25 and 27 KVp, respectively. From Table 3, it is observed that the deviation in measured kVp reaches a maximum value of -5.395% at 27 kVp for unit 2 with W/Rh target filter combinations.

According to IAEA guidelines, the acceptable limit of the percentage of deviation in kVp accuracy is ± 5%. By comparing our results with the limiting value, it is observed that unit 1 with Mo/Rh target filter combinations at 25, 26 and 27 KVp and unit 2 with W/Rh target filter combinations at 27 KVp did not pass the kVp accuracy test. Concerning the differences percentage and COV% of kVp, for unit 1 with different 3 target filter combinations and unit 2 with the limit of IAEA guidelines such as table 2 and 3, it exceeds the limiting value for differences percentage and COV% value at 25 KVp (5.090% and 2.497%, respectively), as shown in table 3. Fig. 1 shows that all 5 target filter combinations of 3 units at 28 KVp have closely measured KVp. So 28 KVp is recommended for clinical use as per IAEA guidelines.

4.2. Half value layer (HVL)

In diagnostic x-ray tubes, the half-value layer (HVL) plays an important role in qualifying the beam and preventing unnecessary radiation exposure.

In this work, HVL for each mammography machine was evaluated at 28 kV with different target filter combinations by adding thin aluminum filters to the X-ray beam and measuring the attenuation in 'good geometry' i.e., for narrow beam conditions to minimize the influence of scattered radiation, then HVL was calculated by using equation (5). HVL was measured for the three-mammography units for all anode filter combinations Mo/Mo, Mo/Rh, and Rh/Rh in unit 1, W/Rh in unit 2, and Mo/Mo in unit 3, and also percentage transmission was calculated, and the results are represented in table 4. The results of HVL at 28 KV were 0.336, 0.389, and 0.395 for Mo/Mo, Mo/Rh, and Rh/Rh, respectively, at unit 1, 0.437 for W/Rh at unit 2, and 0.341 for Mo/Mo at unit 3.

The results of HVL for the three units at all different anode filter combinations were compared to the international standards range required by IAEA. The variations of the HVL in mm Al at 28 kV with different anode filter combinations are plotted in fig.2. The variation of Al-filter thickness with exposure in mR for all anode filter combinations in all units is plotted as shown in fig. 3. From the figure, it was clear that the exposure for all anode filter combinations decreased with a higher Al-filter thickness in mm and a higher atomic number of the filter material. This can be interpreted as the atomic number of the filter material being increased; it attenuates and blocks much of the Bremsstrahlung spectrum. This results in the spectrum that is most often used in mammography, produced with the Mo/Mo combination.

And the k-edge boundary is shifted to a higher energy. This makes the beam more penetrating than when using the lower atomic number filter and provides some advantage when imaging larger or denser breasts. The results showed that all mammography units were considered properly filtered. Since HVL values affect the average glandular dose, the HVL values of all target filter combinations for all units of mammography were measured to assure that the HVL values of the x-ray beam were adequate to minimize breast dose. According to the ACR criteria, at a given kVp setting in the mammographic kilovoltage range, the measured HVL with the compression paddle in place must be equal to or greater than the value: $KVp/100 + 0.03 \leq HVL \leq KVp/100 + C$.

4.3. Tube output measurements

In mammography, a high X-ray tube output is preferred because it enables shorter exposure times, which lessen the impact of patient movement, and provides adequate penetration of large or dense breasts during the current back-up time. The relation between x-ray output and kilovoltage was studied for three units. The COV in output measurements calculated using equation 4 for those three mammography units at various mAs (80, 100, and 125 mAs) at 28 kVp is given in Table 5. From table 5, it is observed that the COV of output reaches its maximum value at 14.865%, and as shown in Fig. 4, output (µGy/mAs) units 1 (Mo/Mo, Mo/Rh, and Rh/Rh) and unit 2 (W/Rh) have almost constant values, and unit 3 (Mo/Mo) has a big variation in output.

As shown in IAEA guidelines, the acceptable limit of the percentage of output COV is 5%; otherwise, units 1 and 2 with Mo/Mo,Mo/Rh, Rh/Rh, and W/Rh combinations passed the output repeatability test. Concerning the output variation with kVp in table 6 at 100, 50 mAs in 3 mammography units, there was a linear relationship between output and kVp (when the kVp increased, the output increased). Tube output is plotted against the tube voltage in fig. 5a and 5b for the four-anode filter combination. A good correlation (average value in unit 1 is 0.998 at Mo/Mo, 0.998 at Mo/Rh, and 0.997 at Rh/Rh; average value in unit 2 and unit 3 is 0.999 and 0.949, respectively) was found between the KVp and measured value of the tube output for the four anode filter combinations.

The result indicated that the values of output were in agreement with the values of the reference level ≥ 30 µGy/mAs for the two anode filter combinations, as shown in IAEA guidelines and the European Protocol. The guidelines of the IAEA and the European protocol show that the linearity of two-tube output at consecutive mAs must be within ≤±10%, and table 7 and fig. 6 show that the three linearities for unit 1 with three target filter combinations and unit 2 with w/Rh combinations are in agreement with the values of the reference level, but unit 3 with Mo/Mo does not occupy the limitation value; L1 and L3 reach the maximum values of 13.5321% and 10.8539%, respectively.

4.4. Compression tests

The compression test was undertaken to check that the mammography system provides adequate compression in manual and automatic modes, to check the accuracy (or deviation) of the indicator of the compression force that is present on the equipment, and to check the accuracy of the compression thickness indicator. The results of the test are presented in Table 8. The acceptable range for the difference value between manual mode and automatic mode at compression alignment and the compression indicator Within mm and for compression force, it must be less than or equal to 20 N. The results of compression alignment at units 1, ,2 and 3 are 1, 1, and 2 mm, respectively; the compression indicator at units 1, ,2 and 3 is 3, 4, and 3 mm, respectively; and the results of compression force at units 1, ,2 and 3 are 4.9 and 10 N, respectively. So the result of all three (3) tests for three (3) units under compression indicates that the system's compression paddle is functioning well at all units tested.

5. Conclusion

This study evaluated different operating parameters through tube voltage (kVp) accuracy and repeatability test, machine output measurement, half value layer measurement, calibration of compression device. The results show that out of three mammography units, only unit one passed all QA tests and the other two units passed three tests only. More efforts are needed to increase the management of breast cancer with improved radiological safety for patients. A facility should strive to ensure that equipment operates at an achievable level of performance, as this will produce the highest image quality and the most appropriate dose performance. It recognized, however, that limited resources, uncorrectable environmental factors, and other factors might prevent the achievable levels from being obtained. In no case should the facility continue to perform mammography if the equipment does not meet the acceptable standard of operation because, below this level, the value of the procedure and/or its safety are considered unacceptable.

6. Recommendation to Ministry of Health

An effective QA program should be practical to implement in diagnostic units, address the various stages of QC testing, be simple to implement, and provide information on equipment performance. This work points out the importance of regulation, and effective compliance also helps in both improving the QA and reducing the glandular dose received by the patients.

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8. Conflicts of interest

There are no conflicts of interest.

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