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EVALUATION OF THE PRIMARY QUALITY CONTROL PARAMETERS ON DIAGNOSTIC RADIOGRAPHIC EQUIPMENT IN GOVERNMENTAL AND PRIVATE HEALTHCARE INSTITUTIONS IN ALBANIA

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Abstract. *During the last decade many European countries have applied and regulated through state legislation quality control (QC) program in diagnostic radiology. Such a program forms an essential part of dose effective radiological practice and should be implemented in every x-ray medical equipment. Implementation of QC tests on diagnostic radiographic equipment can ensure the optimal status of imaging systems, providing in this way high-quality images. QC of radiological medical devices in Albania is applicated since 2015, every three years. QC techniques used to test the components of the radiological system and verify that the equipment is operating satisfactorily are performed from the Institute of Applied Nuclear Physics and all the instruments used for performing these measurements are sponsored by the International Atomic Energy Agency. The aim of this study was to investigate the status of 8 randomly selected X-ray generators used in radiology centers of 6 different cities in Albania during the 2021-2022 period. This study presents only the primary QC parameters: kilovoltage (kVp) accuracy and reproducibility, kVp variation with change of mA, exposure time accuracy and reproducibility, tube output and reproducibility, tube output variation with change in indicated tube current - exposure time product (mAs) and filtration (half value layer). All measurements were performed using Radcal (AGMS-DM+) solid-state multi sensor, plugged into its appropriate (Accu-Gold+) digitizer module. This detector was placed on the radiographic tabletop along with the central axis of the X-ray beam at the focus to detector distance of 100 cm. Based on the findings, this study showed clearly that all the radiographic devices, subject of routine quality control tests were in a very good compliance with the acceptable criteria. Specifically, for the primary QC parameters tests, kVp accuracy was between 1.4 - 5%, kVp reproducibility was between 1-3.1%, kVp variation with change of mA was between 1.4 - 5.4 %, time accuracy and reproducibility was between 0 - 6.6%, tube output value with a total filtration 2.5 mm Al at 100 cm for true 80 kV operation was between 26.1 - 60μGy/mAs, tube output reproducibility was between 0 – 2.5%, tube output variation with change of mAs product was between 1 - 18% and filtration at 70 kV was between 2.6 – 3.9 mm Al. Results of this study showed that, even though radiological devices in Albania are relatively old with high workload, especially during the last years, all the devices met the standard criteria.*

Keywords: *quality control, diagnostic, radiographic equipment, solid state detector*

1. Introduction

Establishment of a quality control program for diagnostic radiographic equipment and the obtained images from them avoids incorrect and non-conclusive diagnoses that could lead to an unnecessary further exposure of the patient and to any possible risk due to the radiography repetition. The number of radiographic exposures within one examination must be kept to a minimum consistent with obtaining the necessary diagnostic information. Quality control techniques represent those techniques used in the continuous monitoring and maintenance of the technical components of X-ray medical equipment.

Periodical verification of technical parameters for the X-ray medical equipment aims to improve the image quality, reduces the patient exposure, eliminates any radiation that does not contribute to the obtaining of useful images, but only increases the risk to develop diseases in patients. With the increased use of ionizing radiation in medicine came the need to standardize the operational aspects of radiological protection to all the X-ray diagnostic medical equipment. Different international recommendations and guidance are issued concerning the scope of QC tests, instrumentation requirements, frequency of testing and tolerance levels of these equipment [1]-[4]. For all types of diagnostic equipment in use each country should have a regulation specifying not only their pass/fail criteria of acceptability but also the periodic time of technical control of this process. These criteria should be drawn up in response to the European Council Directive 2013/59/Euratom which requires that all Member States shall ensure that the competent authority responsible for ensuring appropriate acceptance measures for radiological equipment takes the necessary action by including if possible, putting these devices out of service [5].

The technical control of radiological medical devices in Albania has started since 2015 and is implemented from the Institute of Applied Nuclear Physics (IANP)

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according to Decision No.404 – "On basic rules of radiologic installations in medicine" of the Albanian Ministry of Health which was approved on 18.06.2014 and entered into force six months after the date of its approval [6]. This decision emphasizes that all the radiological equipment used in Albania are obliged to pass in the periodical process of technical control not less than once in three years. QC parameters tests performed and assessed in this study are: kilovoltage (kVp) accuracy and reproducibility, kVp variation with change of mA, exposure time accuracy and reproducibility, tube output and reproducibility, tube output variation with change in indicated tube current - exposure time product (mAs) and filtration (half value layer - HVL).

The purpose of this work was to evaluate the operating conditions of radiographic equipment in use in various health care institutions in different cities of Albania comparing the obtained data with those defined in the actual national radiation regulation. Such measurements are important both for the optimization of image quality and for radiation protection purposes and constitutes a part of the Albanian state effort in radiation protection of patients in diagnostic.

2. Materials and methods

Evaluation of the primary QC parameters tests measurements on diagnostic radiographic equipment in 6 governmental and 2 private healthcare institutions in Albania presented in this study is carried out by laboratory of QC of X-ray medical devices, part of IANP, Albania using a Radcal (AGMS - DM+) solid-state multi sensor plugged into its appropriate (Accu-Gold+) digitizer module. This solid-state detector is used for dental X-ray, radiography/fluoroscopy, and mammographic range measurements. It is capable of measuring kVp, dose, dose rate, pulse, pulse rate, dose/frame, time, HVL, total filtration and waveforms, automatically recording the measurements for each exposure by Accu-Gold Software. The kVp measurement range is 21-160 kV with uncertainty of ± 2%, the dose measurement range is 40 nGy - 100 Gy with uncertainty of ±5%, the HVL measurement range is 1.3-13.5 mm Al with uncertainty of ±5% and the dose rate measurement range is 40 nGy/s - 200 mGy/s with uncertainty of ±5%.

The measurements are carried out placing the detector on the center of the radiographic tabletop at a fixed focus to detector distance (FDD) of 100 cm, perpendicular to the anode–cathode axis of the X-ray tube. The smallest field size possible was selected around the detector with proper collimation ensuring a narrow beam geometry to minimize scattering [7], [8]. All the data were collected from QC tests carried out between 2021-2022 during the regular technical control requests received at IANP from different health care institutions and all statistical analyses were performed using Microsoft Excel Software. A brief description of each QC test measurement included in this study and the acceptance limits of pass/fail criteria [9]-[11] is presented in the following subsections.

2.1. Kilovoltage accuracy and reproducibility

Accuracy of tube voltage is important as even a minor variation will have considerable effect on the contrast of the image and the intensity reaching the image receptor. To make sure that an X-ray generator could provide the same voltage as selected on the equipment control panel, the kVp accuracy of each X-ray machine was determined using Equation 1. According to Albanian regulation the maximum deviation of the measured value from the nominal set value should be less than 10%.

$$kV_p accuraccy = \frac{kV_{measured-kV_{set}}}{kV_{set}} \text{x}100 \qquad (1)$$

To determine the variation in average kVp over several exposures with the same generator kVp setting at least three exposures were performed at constant tube currents and time to enable statistical analysis on the obtained data. Afterward, kilovoltage reproducibility was calculated and for all generators for repeated measurements the deviation in the tube voltage should be less than ± 5% from the mean value.

2.2. Kilovoltage variation with change of mA

Performing this test the x-ray generator should provide the same voltage as the one selected on the equipment control panel for different values of the tube current. The maximum deviation of the measured kVp value from the nominal set value should be less than 10%.

2.3. Exposure time accuracy and reproducibility

An accurate exposure time is important for proper radiographic exposure and reasonable patient radiation exposure. The method applied for the assessment of timer accuracy and reproducibility is the same as the one used for kVp parameter test. For indicated exposure times greater than 100 ms the actual exposure time should be within ± 10% of the indicated exposure time. The time reproducibility should also be less than ± 10 % from the mean value.

2.4. Half-Value Layer/filtration

Filtration is used to remove the lower energy from the primary X-ray beam before contact with the patient. Use of the proper possible filtration avoids the X-ray energy that does not contribute to the formation of the image. The material generally used to determine the HVL is aluminum. With the purpose of controlling this process total filtration in the useful beam should be equivalent to not less than 2.5 mm Al.

2.5. Tube output and reproducibility

For a magnitude with a total filtration of 2.5 mm Al, the tube output should be greater than 25 μ Gy/mAs at 100 cm for true 80 kVp operation ensuring in this way that there is no need for the radiologic technologist to use a long exposure time which could lead to a degradation of image quality. For repeated exposures the reproducibility of the tube output should be constant within ± 20% of the mean.

*2.6. Tube output variation with change in indicated tube current - exposure time product (I*t)*

In general radiography the default spectrum should provide energies that provide an appropriate trade-off between radiation dose and image quality. The radiation output of the radiographic X-ray system at a specific tube voltage should remain constant when a given current–time product is selected in any combination of current and time. The tube output variation with change in indicated tube current - exposure time product should be less than 20%.

3. Results and discussions

For reasons of identity protection hospitals that were part of this study are marked with letters A, B, C, D, E, F, G, H. Selection of the X - ray machine units are based on the time they have been in use which varies from 4 to 22 years. The radiographic equipment subject to the QC tests measurements belongs to different manufacturers:

- Siemens - hospital A
- Apelen - hospital B
- Philips - hospital C, D and G
- Toshiba - hospital E, F
- Shimatzu - hospital H

Table 1. measurement results for Dose (mGy) and HVL (mm Al) at 60-90 selected kVp and 1.7-125 mAs product(I*t)

Hospital	Set kV	Measured kVp	Dose (mGy)	HVL (mm Al)
A	60	60.1	3.54	2.5
	70	69.0	0.03	3.9
	80	80.2	0.56	4.7
	90	91.1	0.73	5.1
B	60	61.2	0.36	2.5
	70	70.3	0.50	2.9
	80	81.1	0.67	3.3
	90	92.3	1.05	3.6
C	60	61.3	0.38	2.5
	70	70.8	0.54	2.9
	80	82.4	1.47	3.4
	90	92.1	1.46	3.7
D	60	62.6	0.07	2.9
	70	73.5	0.10	3.4
	80	81.7	1.88	4.0
	90	91.9	2.48	4.4
E	60	61.2	0.07	2.3
	70	70.1	0.51	2.6
	80	81.2	1.03	3.0
	90	92.0	1.86	3.3
F	60	60.4	0.17	2.6
	70	70.9	0.38	3.0
	80	82.6	0.78	3.4
	90	93.9	1.31	3.8
G	60	60.7	0.26	3.1
	70	70.3	0.42	3.5
	80	81.9	4.67	4.1
	90	91.3	4.75	4.5
H	60	60.6	0.32	2.3
	70	71.4	0.45	2.6
	80	81.5	0.75	3.0
	90	91.4	0.22	3.2

To investigate kVp accuracy, dose and HVL the most used clinical tube voltages 60 - 90 kVp were measured with tube currents and time production (I*t) ranged from 1.7 - 125 mAs. Records were automatically made for each 10 kV step. The results of these measurements are reported in Table 1.

As shown in Table 1, for tests carried out at 70, 80 and 90 kV the HVL measurements results are greater than 2.5 mm Al. For tests carried out at 60 kV, the HVL measurements results varies from 2.3 to 3.1 mm Al. For HVL testing more detailed specifications need to be included in our national regulation. As long as they are not available so far, then we have to refer to international recommendations, national professional guidelines or peer-reviewed scientific literature [12], [14]. Measurement results for the total filtration test are reported in Table 2.

Table 2. Measurement results for total filtration

kVp	Total filtration (mm Al) /Hospital							
	A	B	C	D	E	F	G	H
60	3.6	3.3	3.3	4.7	2.7	3.4	5.1	2.8
70	6.3	3.4	3.5	4.8	2.8	3.4	5.1	2.9
80	6.4	3.4	3.4	4.8	2.7	3.3	5.0	2.8
90	6.4	3.3	3.4	4.7	2.7	3.3	4.9	2.8

From the reported results in table 2, it can be clearly seen that total filtration is greater than 2.5 mm Al for all equipment investigated at each kVp values selected. So, total filtration is in very good agreement with the acceptance criteria according to our national radiation protection regulation for all the radiological devices investigated.

Radiation output expressed in µGy/mAs was measured at 80 kV setting, with 100 cm FDD. Radiation output variation with change of mAs, was also measured at 80 kV with 100 cm FDD and is expressed in percentage. Figure 1 presents the results of radiation output measurements and the maximum deviation of radiation output variation with change of mAs for eight radiological equipment investigated at A, B, C, D, E, F, G, H hospitals.

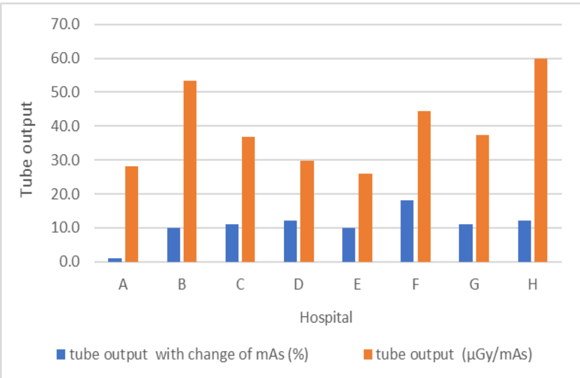

Figure 1. tube output (µGy/mAs) results at 80 kVp, 100 cm FDD, and tube output variation with change of mAs (%), for eight hospitals

As shown in Figure 1, reported values for tube output ranged from 26.1 – 60 (µGy/mAs), indicating that all the tube radiation output values are greater than 25 µGy/mAs, being in a very good agreement with the acceptance criteria specified in Albanian regulation. For tube output variation test with change of mAs product the minimum deviation is 1.0% for hospital A, while maximum deviation is 18 % for hospital F that means it is close to the upper specified limit for this hospital.

Therefore, we recommended to this healthcare institution more frequent testing of its radiographic equipment in the future to monitor the equipment's stability over time. Based on this radiographic equipment performance trend corrective action should be initiated by this institution.

Table 3 presents the measurements results for maximum deviations in percentage terms taken for QC parameters tests performed for radiographic equipment at A, B, C, D hospitals while in Table 4 are reported the measurements results for QC parameters tests performed for radiographic equipment at E, F, G, H hospitals.

Table 3. Measurement results of QC parameters tests for radiographic equipment at A, B, C, D hospitals

Nr	QC parameter test	Max deviation (%) Hospital			
		A	B	C	D
1	kVp accuracy	1.4	2.6	3.0	5.0
2	kVp reproducibility	1.0	1.6	2.9	2.1
3	time accuracy	6.0	0.0	0.4	1.0
4	time reproducibility	4.3	0.0	0.4	0.2
5	kVp variation with change of mA	2.1	1.4	3	2.2
6	tube output reproducibility	2.5	0	0	0

Table 4. measurement results of QC parameters tests for radiographic equipment at E, F, G, H hospitals

Nr	QC parameter test	Max deviation (%) Hospital			
		E	F	G	H
1	kVp accuracy	2.2	4.3	2.4	2.0
2	kVp reproducibility	1.4	3.1	2.4	1.9
3	time accuracy	6.6	0.0	0.3	0.0
4	time reproducibility	6.6	0.2	0.4	0.0
5	kVp variation with change of mA	1.5	5.4	2.3	2.0
6	tube output reproducibility	0.8	1.5	0.0	0.2

From the reported results shown in these two tables it can be concluded that for kVp accuracy test, the minimum deviation is 1.4% and belongs to hospital A, while maximum deviation is 5% and belongs to hospital D. For kVp reproducibility test, the minimum deviation is 1.0% hospital A, while maximum deviation is 3.1% hospital F. For the time accuracy test, the minimum deviation is 0% hospital B, F and H and maximum deviation is 6.6% hospital E. For the time reproducibility test the minimum deviation is 0% hospital B and H, while maximum deviation is 6.6% hospital E. For kVp variation with change of mA test, the minimum deviation is 1.4% hospital B while, maximum deviation is 5.4% hospital F. For tube output reproducibility the minimum deviation is 0% hospital B, C, D and G while maximum deviation is 2.5% hospital A.

It can be clearly seen that these tests are within the specified limits in our national regulation for all the radiological devices investigated in this study. Consequently, ensuring that all the parameters measured in this study are within the tolerances recommended by international protocols we concluded to an optimal performance for all the investigated equipment.

4. Conclusion

Evaluation of the primary QC parameters tests measurements on diagnostic radiographic equipment in 6 governmental and 2 private healthcare institutions in Albania are presented in this paper with the purpose of obtaining images with optimal quality and maximum diagnostic information as a benefit for patient's health. All measurements were carried out using Radcal (AGMS-DM+) solid-state multi sensor.

Based on the findings the kVp accuracy fulfilled the criteria lower than 10 % being between 1.4 - 5%, kVp reproducibility fulfilled the criteria lower than 5% being between 1-3.1%, time accuracy and reproducibility fulfilled the criteria lower than 10 % being between 0 - 6.6%, kVp variation with change of mA fulfilled the criteria lower than 10 % being between 1.4 - 5.4 %, tube output fulfilled the criteria greater than 25 μGy/mAs being between 26.1 – 60 μGy/mAs, tube output reproducibility fulfilled the criteria lower than 20 % being between 0 – 2.5%, total filtration fulfilled the criteria being greater than 2.5 mm Al. The tube output variation with change of mAs product test, fulfilled the criteria lower than 20 % being between 1 - 18% but for this test the maximum deviation for hospital F is closer to the upper limit showing that in this case there is a considerable range of variation.

Thus, we recommended to this healthcare institution more frequent testing of this radiographic equipment to monitor the equipment's stability over time. This study clearly showed that even though radiological devices in Albania are relatively old with high workload especially during the last years all the X-ray medical devices met the standard criteria specified in our national radiation protection regulation. Reporting a good accuracy and precision of all the X-ray equipment by applying a periodical safety quality control process we ensure that all patients and personnel part of Albanian healthcare institutions do not receive unnecessary doses.

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