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An Enumeration Survey on Diagnostic X-Ray Generators and Essential Safety Parameters in Mizoram, India

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ABSTRACT

Introduction: Best radiography practice involves operational optimal machine performance, delivering cost-effective healthcare services under appropriate safety conditions for workers and the public. The present study aimed to investigate the safety status of diagnostic X-ray installations in Mizoram, India.

Material and Methods: Linearity of time (sec), linearity of current (mA), output reproducibility, table dose (µGy/mAs), peak voltage (kVp) accuracy, and 16 essential safety parameters of 135 X-ray machines were considered in this study. A battery-operated dosimeter and wide-range digital kVp meter were used to measure output radiation and effective peak potential of X-ray tube. Data analysis was performed using SPSS software to obtain the mean, standard deviation, and coefficient of variation.

Results: Among different electronic parameters, 59.2% linearity of time, 82.6% linearity of current, 89.7% kVp accuracy, 35.1% output reproducibility, and 92.8% table dose were beyond the acceptable limits. Based on 16 essential safety parameters, it was observed that 98.7% of X-ray machines did not receive proper quality assurance test, 1.9% of the installations employed lead-line patient entrance doors, 46.8% of the machines were operated without any protective barriers and 83.1% of the units were operated without personnel monitoring service.

Conclusion: The present study had concluded with more problems than the previous studies in different parts of the world in this regard. Due to the absence of proper quality control (QC) programs, many installations did not follow standard installation guidelines. The authors recommended that proper QC should be implemented by the frequent monitoring of each and every diagnostic X-ray installation.

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Introduction

An X-ray machine is a device that is regularly used to diagnose various diseases [1]. Extensive clinical use of this equipment has resulted in enhanced exposure to radiation among workers and patients [2]. The X-ray radiation is one of the major artificial sources of ionizing radiation to humans [1]. Therefore, regarding radiation protection, the patients' and workers' exposure to radiation due to diagnostic X-ray machines is a very important cause of concern [3]. It is well-known that the protection from radiological exposure relies on the basic principles, namely dose limitation, optimization, and justification [4]. Optimization in radiological exposure indicates that the ionizing radiation dose applied for the patients should be at the lowest possible level; however, it should be at par with the radiological image quality necessary to obtain an adequate diagnosis or to guide the treatment [3]. In other words, radiation exposure should be as low as reasonably achievable (ALARA)[5].

Implementation of quality assurance (QA) programs in diagnostic radiology was carried out in order to achieve the ALARA principle [6, 7]. In order to reduce radiation exposure, to lower medical costs, and improve the available diagnostic information, the World Health Organization has increasingly highlighted the importance of QA programs [8]. Furthermore, the aim of QA was to produce X-ray images with the best quality and lowest possible dose delivered to the patient to minimize the production of rejectable images. By applying such QA programs, some other economic advantages may be achieved, namely extended life spans of X-ray machines and reduced number of rejected image films [9].

The present study was a complete enumeration survey on QA assessment conducted during June 2015 to June 2016 throughout Mizoram, India. In total, there were 195 X-ray facilities, out of which 26 equipment was condemned because the equipment were beyond repair. Among different X-ray facilities, 135 (69.2%) equipment was conventional diagnostic X-ray units, and 90.9% of the total workload (5687.21 mA-min/weeks) was performed in the conventional X-ray (Table 1). The detailed calculation was reported in a previous study [10, 11].

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Table 1. X-ray facilities and their respective workloads in Mizoram, India, during June 2015-June 2016

Type of X-ray facilities	Total	Conventional X-rays	Dental X-rays	Others*
X-ray facilities	195	69.2%	23.1%	07.7%
Condemn X-ray	26	92.3%	7.7%	Nil
Workload (mA-min/week)	5687.21	90.9%	2.5%	6.6%

* (Cath-Lab, Computed Tomography Scan, Fluoroscopy, and Mammography)

The present study dealt with these 135 diagnostic machines. Mean age of the entire X-ray machines was reported as 7.20±6.69 years, and the oldest unit was installed 44 years ago. Quality parameters of the X-ray generators considered in this study included the linearity of time (sec), linearity of current (mA), output reproducibility, peak voltage (kVp) accuracy, table dose (μGy/mAs), and other 16 important safety parameters. To the best of our knowledge, no such study had been performed or reported in this regard. The obtained results were compared to the standard safety limits recommended by various regulatory bodies [7, 12−17]. Furthermore, the aforementioned findings were compared to the results of previous studies [9, 18–28].

Materials and Methods

Figure 1 depicts the locations and details of 135 machines installed in 82 institutions. However, the electronic parameters could not be measured from all 135 conventional diagnostic X-ray machines because 24 machines were condemned, others were out of order, and some of the installations were reported with power supply problems. Among 111 diagnostic X-ray machines, the oldest X-ray machine was installed in 1972. A total of 13, 45, and 53 X-ray machines were installed during the years 1972-2000, 2001-2010, and 2011-2016, respectively.

Linearity of time (sec) and current (mA), as well as tube output reproducibility, were measured by setting 100 cm focus to detector distance (FDD). Size of the radiation field was adjusted in order to cover only the sensitive area of the detector to avoid secondary radiation to the detector. A battery-operated portable dosimeter (Rad-Check^{TM}Plus model 06-526, Fluke Biomedical-Cleveland, Ohio, USA) was used for the measurement of the output radiation of X-ray generators. The calibration measurements were similar to those of the National Institute of Standards and Technology. By an internal ionization chamber, X-ray exposure was measured in Roentgens with a minimum value of 0.001 R and maximum value of 1.999 R(or 2.58×10^{-7} to 5.16×10^{-4} C/kg in standard unit), respectively [29].

A portable wide-range digital kVp meter (model 07-494, Fluke Biomedical-Cleveland, Ohio, USA); battery-operated unit was used to measure the effective peak potential applied to a target of X-ray tube noninvasively. The kVp measurement is computed from a measurement of the linear absorption coefficient (μ) of the hardened X-ray beam. It uses two differentially filtered X-ray detectors and the digital kVp meter can measure peak potential between 50-150 kVp with 0.1 kVp resolution [30]. A total of 16 other important survey parameters, such as X-ray room layout, frequency of QA, patient entrance door (PED), and personnel monitoring service (PMS), were considered by observation and interview methods. Data analysis was performed using SPSS software (version 17.0) in order to obtain mean, standard deviation, and coefficient of variation (CV).

Output Linearity of Time

To measure the output linearity of time (sec), input voltage and current were fixed, and at least four exposures were conducted at the intervals of 0.2, 0.4, 0.6, and 0.8 sec. For particular exposure time (i.e., 2 sec), not lower than three exposures were performed with the same input parameters for the calculation of the average value. The *X* parameters defined as dose to mAs ratio were calculated for each exposure time setting. Then, the coefficient of linearity (*CL*) was measured using equation 1[12, 13, 17, 18]. Among 135 conventional diagnostic X-ray machines, the linearity of time was calculated from 98 (72.6%) units.

$$CL_{(sec)} = \frac{\overline{X}_{max} - \overline{X}_{min}}{\overline{X}_{max} + \overline{X}_{min}} \quad (1)$$

Where $\overline{X} = \frac{Avg.Dose}{mAs}$ the *CL* should be lower than 0.1 [13, 14, 17].

Output Linearity of Current

Linearity of a radiation output as a function of current was determined by setting constant tube voltage and time of exposure. Four successive exposures were performed with the tube current intervals of 50, 100, 200, and 300 mA. For a particular tube current, at least three exposures were given with the same input parameters for the calculation of average measurement. The X parameters were defined as dose to mAs ratio and were calculated for each tube current setting. The CL calculated based on equation 2[13, 17] was set at <0.1 [12–17].Linearity of the current was measured from 69 (51.1%) X-ray machines. Diagnostic X-ray machines that can operate only at a particular fixed current (mA) due to malfunction in mA loading station also existed other than condemned and out of order machines.

$$CL_{(mA)} = \frac{\overline{X}_{max} - \overline{X}_{min}}{\overline{X}_{max} + \overline{X}_{min}} \quad (2)$$

Where $\overline{X} = \frac{Avg.Dose}{mAs}$

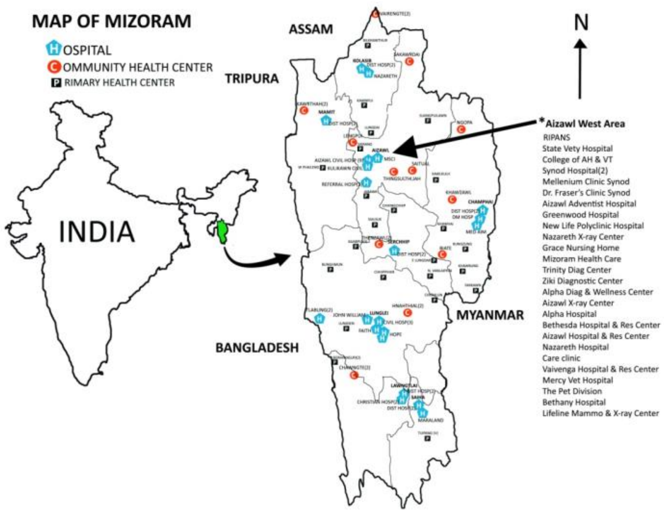

Figure 1. Location of 135 installed X-ray machines in 82 different institutions

Output Reproducibility

At constant tube voltage and tube loading, not lower than five exposures were performed to evaluate X-ray tube output reproducibility. The *CV* obtained from equation 3 was accepted at<0.05 [7, 13–17]. Reproducibility of tube output was considered according to 97 (71.9%) conventional diagnostic X-ray machines.

$$CV = \frac{1}{\overline{X}}\sqrt{\frac{\sum_{i=1}^{n}(X_i - \overline{X})^2}{n-1}} \quad (3)$$

Tube Output (70 kV at focus to detector distance=100 cm)

At tube voltage 70 kVp and typical tube loading, the X-ray dose was measured at 100 cm FDD that can be used for the evaluation of the patient's skin dose[18]. The table doses obtained from equation 4 were expected to be within the range of 43-52 µGy/mAs[15].Tube output could be measured from 97 (71.9%) units.

$$X = \frac{Avg.Dose}{mAs} \quad (4)$$

kVp Accuracy

To evaluate kVp accuracy, the authors measured accelerating potential from 50-150 kVp (5kVp steps) where tube loading and FDD were set as per Fluke manual for different accelerating potentials [30]. For example, when the peak potential is set at 70 kVp and FDD 18in., the mAs required is 20. Again, for 100 kVp and 30 in. FDD, the mAs 62.5 is required. In some equipment, it was impossible to set kVp at higher than 90 due to improper and insufficient power supply. Voltage accuracy expected to be within ±5 kV was considered based on equation 5 [7, 13–15]. From 135 conventional units, kVp accuracy could be measured from 97 (71.9%) machines.

$$VoltageAccuracy = \frac{kV(measured) - kV(selected)}{kV(selected)} \quad (5)$$

Other Safety Parameters

Other than diagnostic X-ray generator parameters, the researchers obtained the data from 16 important safety parameters. The aforementioned data related to the parameters of the frequency of QA, X-ray room layout, availability of PMS, lead apron, gonad shielding, repeated exposure and repetition reason, qualified personnel, collimator bulb, field size knob, PED, protective barrier, waiting area, chest stand, warning light, and dark rooms, were checked and recorded. This information was collected from radiation workers and/or heads of institutions belonging to Mizoram, India through observation and interview methods.

Results

Linearity of Time

Out of 98 X-ray machines tested for the linearity of time (sec), 58 (59.2%) units had the CL above 0.1 (Figure 2); however, only 40 (40.8%) units were within the acceptable limits. The highest value for the CL of time was 0.93; nevertheless, the mean value was reported as 0.20±0.19 in this regard.

Linearity of Current

Out of 69 X-ray machines tested for the linearity of current, 57 (82.6%) units had the CL above 0.1 (Figure 3). Only 12 (17.4%) tested units were within the norms. The highest value for the CL of current was 0.97, and the mean value was obtained at 0.25±0.18 in this regard.

Output Reproducibility

Out of 97 X-ray machines tested for output reproducibility, 34 (35.1%) units were tested above 0.05 (Figure 4). The remaining 63 (64.9%) X-ray machines were within the acceptable limits. The calculated mean value was 0.08±0.12, and the highest value of tube output CV was reported as 0.72.

Tube Output (70 kV at focus to detector distance=100 cm)

Tube output at 70 kVp (i.e., table dose) was measured from 97 conventional diagnostic X-ray machines. In this regard, 90 (92.8%) units had table doses beyond 43-52 µGy/mAs (Figure 5), and only 7 (7.2%) machines were within the acceptable limits. The highest and lowest values of tube output (i.e., table dose) were 236.82 and 1.57 µGy/mAs, respectively, with a mean value of 31.00±33.63 µGy/mAs.

kVp Accuracy

Voltage accuracy measured from 97 conventional diagnostic X-ray machines showed that 87 (89.7%) units had CV beyond ±5 kV (Figure 6), with only 10 (10.3%) units recording variation within the acceptable limits.

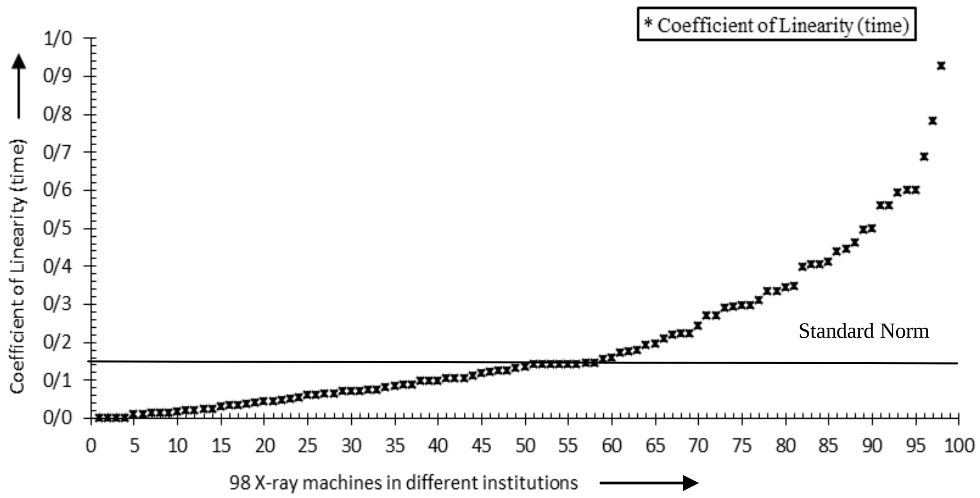

Figure 2.Tube output linearity of time (sec) for 98 conventional diagnostic X-ray machines

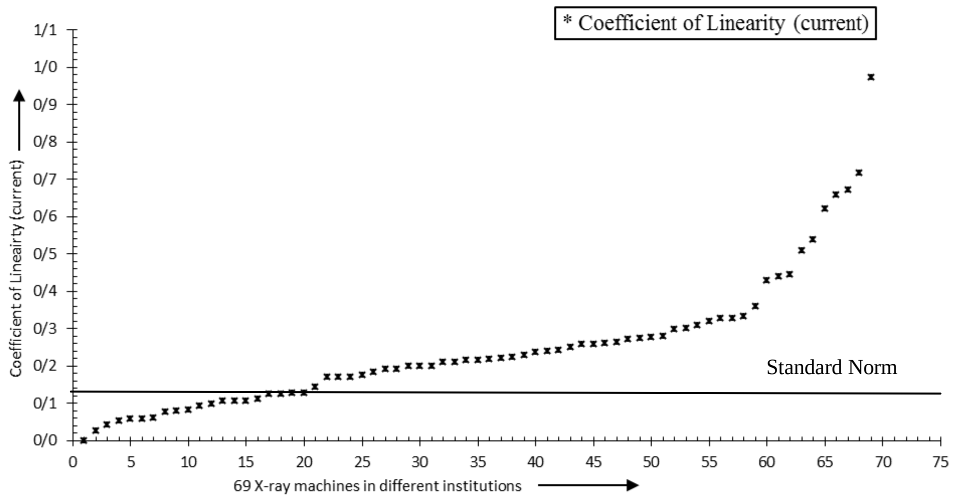

Figure 3. Tube output linearity of current (mA) for 69 conventional diagnostic X-ray machines

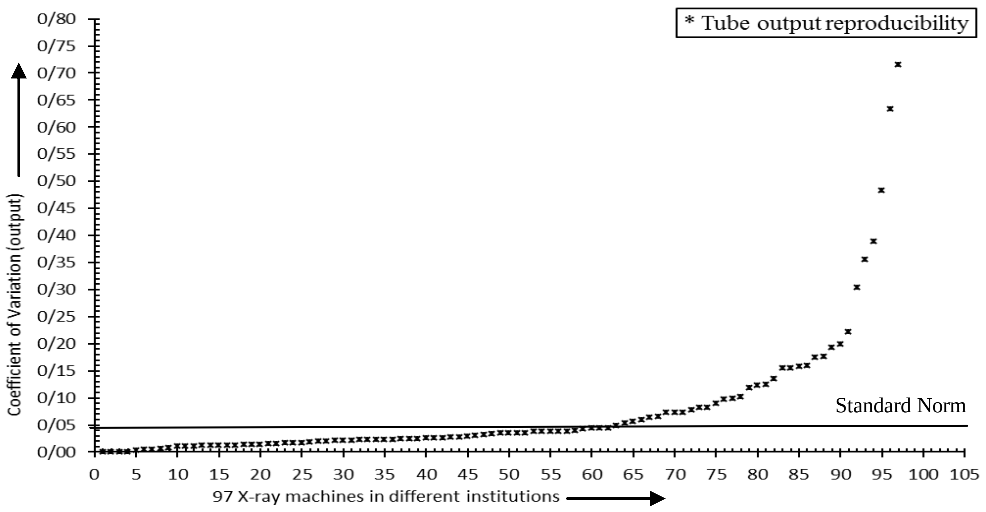

Figure 4.Tube output reproducibility for 97 conventional diagnostic X-ray machines

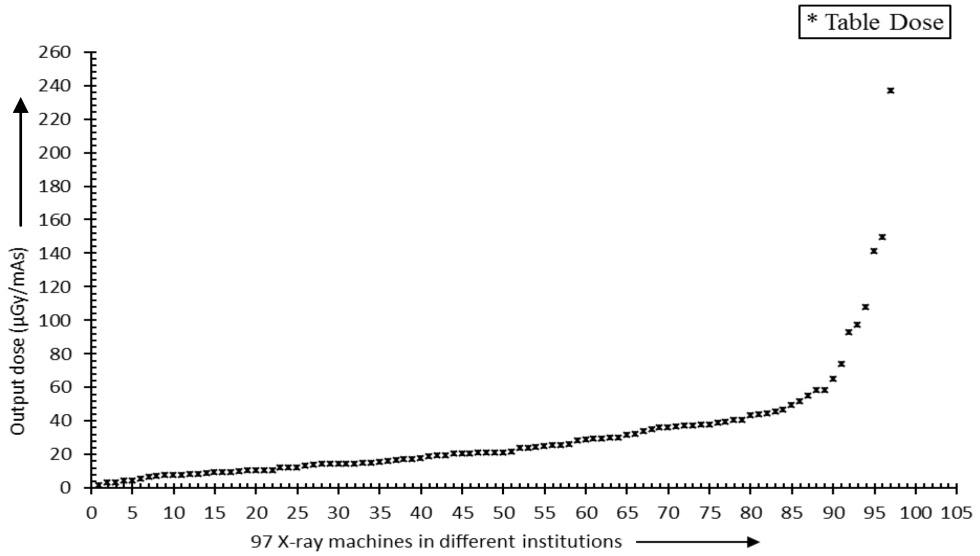

Figure 5. Tube output (kV=70) for 97 conventional diagnostic X-ray machines

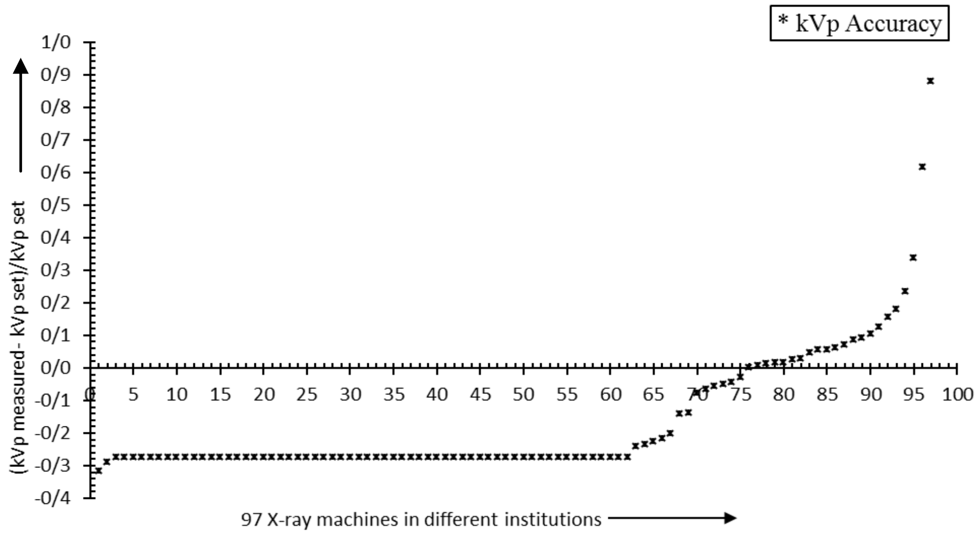

Figure 6. Voltage accuracy for 97 conventional diagnostic X-ray machines

Table 2.16 important safety parameters in diagnostic X-ray installations

Sl/ No.	Parameters	Variables	Number of units	Percentage (%)
1.	Types of X-ray (155 X-ray machines)	1. Fixed X-ray	046	29.7
		2. Mobile-fixed X-ray	102	65.8
		3. Mobile X-ray	007	04.5
2.	Frequency of quality assurance (155 X-ray machines)	1. Regular	000	0
		2. Once	002	01.3
		3. Never	153	98.7
3.	PED (155 X-ray machines)	1. Lead lining	003	01.9
		2. No lead lining	145	93.6
		3. No door	007	04.5
4.	Protective barrier (154 X-ray machines)	1. With lead glass	057	37.0
		2. Without lead glass	025	16.2
		3. No barrier	072	46.8
5.	Waiting area (154 X-ray machines)	1. Away from PED	131	85.1
		2. Near PED	020	13.0
		3. Inside	003	01.9
6.	Chest stands (154 X-ray machines)	1. Away from PED and window	132	85.7
		2. Near PED	012	07.8
		3. Near window	010	06.5
7.	Warning lights (154 X-ray machines)	1. Available and working	024	15.6
		2. Available but not working	002	01.3
		3. Not available	128	83.1
8.	Personnel monitoring service(154 X-ray machines)	1. Available and used	018	11.7
		2. Available but not used	008	05.2
		3. Not available	128	83.1
9.	Lead apron (154 X-ray machines)	1. Available and used	081	52.6
		2. Available but not used	014	09.1
		3. Not available	059	38.3
10.	Gonad shielding (154 X-ray machines)	1. Available and used	007	04.6
		2. Available but not used	000	0
		3. Not available	147	95.4
11.	Dark room (154 X-ray machines)	1. Computed radiography	035	22.7
		2. Completely dark	111	72.1
		3. Partial dark	008	05.2
12.	Repeated exposure (154 X-ray machines)	1. Mostly	002	01.3
		2. Sometimes	142	92.2
		3. Never	010	06.5
13.	Repetition reason (155 X-ray machines)[a]	1. Over/Under exposure	080	34.9
		2. Film spoil	033	14.4
		3. Patient movement	116	50.7
14.	Collimator bulb (152 X-ray machines)	1. Available and working	129	84.9
		2. Available but not working	011	07.2
		3. Not available	012	07.9
15.	Field size knob (154 X-ray machines)	1. Available and working	141	91.6
		2. Available but not working	004	02.6
		3. Not available	009	05.8
16.	Personnel (154 X-ray machines)	1. Qualified	143	92.9
		2. Not qualified	001	00.6
		3. Not available	010	06.5

[a]The percentage was calculated based on 229 X-ray machines because some installations simultaneously had one or more problems.
PED: Patient entrance door

Other Safety Parameters

Assessment of 16 important safety parameters through observation and interview revealed that none of the facilities performed a regular QA test since the installation. In addition, 98.7% of the X-ray machines did not receive proper QA tests as recommended by the regulatory body of the Atomic Energy Regulatory Board (AERB) in India [16]. Concerning PED, only 1.9% of the installations employed lead-lined PED, and the rest used a typical wooden door, plywood-lining door, and plane-sheet lining door. Out of 154 X-ray machines, 46.8% of them were operated without any protective barriers. In addition, 61.7% of the installations were equipped with lead aprons.

Regarding PMS, only 11.7% of the X-ray machines maintained and used PMS properly; however, 83.1% of the machines were operated without PMS. Only 15.6% of the X-ray machines had working warning lights outside the X-ray rooms or patient waiting areas. In addition, 92.2% of the facilities recorded repeated examinations due to over/underexposure, spoilt films, and patient movement. Table 2 tabulates the obtained results of some other important parameters that affect the quality of the image, as well as safety of the population.

Discussion

In the initial stage of the present investigation in 2015, the majority of the radiographers and institutional heads were not acquainted with the benefits and significance of X-ray QA test. Furthermore, none of the installations were registered in regulatory bodies nor licensed under the AERB. The main reason was that the present study domain was one of the economical backward areas and was located in the remote part of northeast India where there is poor infrastructural base in almost every discipline. However, through Radiation Safety Agency of Mizoram mission in March 2019, 124 (73%) installations were licensed under the AERB in India [31].

A total of 59.2% X-ray machines were out of the acceptable limits in radiation output linearity for time. In previous studies, the output linearity of time for 8.9-12% of the machines was observed to be beyond the acceptance limits[19, 20]. Rasuli et al. in 2015 demonstrated that all the measured devices were in line with the standard norms[18]. However, X-ray generators vary in performance from place to place and even in the same place from machine to machine. Regarding the output linearity of current, 82.6% of the machines were out of the acceptable limits in the present study. Nevertheless, 12-55% was observed in previous studies in different parts of the world[18−26].

Moreover, in the output reproducibility test, 35.1% of the machines were out of the acceptable limits. According to the results of previous studies in different regions, it was observed that 5-30% of the devices were out of the acceptable limits [20-23, 25, 26]. However, Rasuli et al. noticed that all the measured devices were in line with the acceptable limits[18].At the same time, in the kVp accuracy test, 89.7% of the machines were out of the acceptable limits. Nonetheless, in a previous study, 11-59% intolerance was observed in different regions of the world [9, 18–28].

It is demonstrated that there are more problems regarding X-ray generators in the present study than in previous studies that maybe due to several reasons. Firstly, as mentioned earlier, none of the X-ray equipment had regular QA tests in the past years. For most machines, this survey was the first QA test according to the AERB guidelines. Secondly, some of the machines were worn out and were used without proper maintenance (i.e., records) for long periods of time. At least, 28% of the machines were installed more than 10 years ago. Thirdly, in peak hours, the X-ray machines did not receive the required power supply, and in some areas, the power supply was provided with voltages lower than 150 V considered to be 220 V in the present study area.

Faults in the linearity of time, linearity of current, output reproducibility, and kVp reproducibility can cause repeated exposure that in turn increases the radiation dose, cost of imaging, and duration of imaging. In a similar study carried out by Hassan et al., it was concluded that the total absorbed dose delivered to different organs mainly depends on the X-ray generators [32].

It was noticed that some of the machines had table doses as high as 236.8 µGy/mAs. This may increase the patient dose, as well as doses for the workers, through primary and scattered radiation. The X-ray generator that produced only 1.57 µGy/mAs table doses was also observed in this study. In this situation, repeated exposure may occur due to under exposure. To compensate, radiation workers required increase in the input parameters, which may increase stray radiation. Furthermore, repeated exposure is time-consuming and expensive for the patient and workers. Simultaneously, in 92.8% of the X-ray machines, table dose was out of the standard limits. However, in a study carried out by Rasuli et al. during 2015 in Khuzestan, Iran, 46.7% of the X-ray machines were out of the acceptable limits in this regard [18].

According to the records of 16 essential safety parameters, it is very clear that the majority of the institutions in the present area were not following the installation guidelines laid down by several regulatory bodies. Improper quality control (QC) programs in the past years may be the reason behind all these poor results. This situation increases the risk of radiation effects for the patients, public, and radiation workers as these parameters are directly or indirectly concerned with radiation protection. Moreover, the negative impact may be the underutilization of expensive equipment and less cost-effectiveness of healthcare services.

The authors recommend that proper QC should be implemented immediately by the frequent monitoring of each and every diagnostic X-ray installation every year. In order to achieve the lowest number of machine malfunctioning and produce high-quality diagnostic images with the lowest radiation dose to the patient, it is essential to implement QC programs on a regular basis [2].

There are a few limitations to be noted in the present study. Firstly, as already mentioned, some of the equipment cannot be operated due to insufficient power supply, and few machines were operated at a low input power that may affect the X-ray machine output. Secondly, due to fixed control console switches, a small number of machines cannot be studied in terms of certain input parameters. Thirdly, according to the obtained results of the present study, all possible reasons for such defects could not be clarified, and there is no possibility to repair those machines.

Conclusion

Among different electronic parameters of conventional diagnostic X-ray machines, 59.2% linearity of time (sec), 82.6% linearity of current (mA), 89.7% kVp accuracy, 35.1% output reproducibility, and 92.8% table dose (µGy/mAs) were beyond the acceptable limits. According to 16 essential safety parameters, it was observed that none of the X-ray machines underwent a regular QA test. Furthermore, only 1.9% of equipment employed lead-line PED, and 46.8% of the machines were operated without any protective barriers. Moreover, 83.1% of the units operated without PMS, and the lead aprons were not available in 38.3% of the machines. In addition, 92.2% of the facilities recorded repeated examinations due to over/underexposure, spoilt films, and patient movement.

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