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A Comparative Analysis of Factors Influencing Compliance to Contain Man-Made Ionizing Radiation in Diagnostic Medical Imaging Devices

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Abstract- The unnatural ionizing radiation emanated from Medical Diagnostic Imaging devices particular, CT and X-ray Scanners, contributes more than 50 percent of exposure to radiation globally. The technicians felt the need for deploying new technological equipment use as they consume considerably less dose for diagnosis. Hence, the management of hospitals and diagnostic centers is considering the need for swift adoption of modern and highly innovative equipments for improving patient safety and operational effectiveness. India being a country which encourages refurbished and new medical diagnostic imaging equipment, compliance with regulatory requirements for containing excessive radiation becomes critical. This research study has analyzed regulatory compliance in hospitals and diagnostic centers with 451 samples across the southern part of Tamil Nadu, India. There were seven different dependent variables namely Regulatory, Layout Engineering, Technician Competency, Human Safety, Operations Know-How, Radiation Exposure Monitoring & Top Management Commitment were studied using a structured questionnaire, and Kruskal-Wallis test was performed to compare the radiation compliance score.

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Keywords: ionizing radiation, computed tomography, digital radiography, regulatory compliance, exposure to radiation & man-made radiation.

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I. Introduction

The Healthcare Industry in India is expected to touch 280 billion USD in 2020[1] .The diagnostic medical imaging equipment such as X-rays, Digital radiography, and CT Scans contribute 75 percent of the total market share [2]. The existing doctor and patient ratio in India are1: 30,000, which is far less than WHO recommendation [3] of 1:1000. The refurbishment market for diagnostic medical imaging has been a powerful contributor in India and expected to grow further. More than 200 Billion USD investment in medical infrastructure creation is projected to fulfill the demands forecasted for Tier II and Tier III cities of Indian market [4] before 2020. Among 106 markets registered for the trading of refurbished medical devices, 85 markets permit the unrestricted importation of used medical devices, including India [5]. Most of the hospitals and diagnostic centers prefer refurbished diagnostic imaging equipment (CT, BMD, X-ray, and Mammography) due to lower cost without compromising the image quality. There have been no restrictions for the importation of the used medical imaging devices until 2015, by the regulator Atomic Energy Regulatory Body (AERB). However, effective September 2015, AERB has made an amendment in the regulatory process which restricts the importation of more than seven years old Pre-owned Medical X-ray equipment in the Country [6]. This change in regulatory norm has necessitated for a comprehensive review of the existing process practices to contain the excessive radiation.

II. Literature Survey

The radiation studies have shown loss of six days of life expectancy due to diagnostic imaging X-rays[7]. The recommended radiation dose for initial diagnosis is between 0.1 and 100 mSv, while for therapeutic radiation it is between 20 - 60 Gy [8]. CT studies have revealed that more than 50 percent of the effective dose was contributed by diagnostic radiology [9]. Exposure beyond threshold levels was reported due to improper adjustments of operational controls [10].There were more than 62 million CT examinations per year [11,

and the increasing number of recommendation for CT scan is a serious cause of concern [12]. Studies have predicted more than 29,000 future cancers could be related to CT Scans [13]. The Exposure Index recommended by equipment manufacturers as a measure of radiation dose effectiveness was found to have inconsistencies [14]. The modern technologically driven radiation equipment offer high precision imaging with low dose levels [15]. These research studies mandate the need for immediate change over to innovative new technology medical imaging equipment by gradually eliminating the use of traditional technology equipments including refurbished X-ray equipments. This, establishes the need for stringent compliance with regulatory guidelines and standards towards protecting the existing installed base of X-ray equipment from excessive ionizing radiation and induce the adoption of newer generation equipment.

Studies related to regulatory compliance to contain ionizing radiation in Diagnostic Laboratories have shown adequate gaps in implementation[16]. Analysis of Regulatory compliance on Radiation Safety Parameters with Chain of Diagnostic Centers has cited lack of Top Management involvement[17]. Research work on 'Factors Influencing regulatory compliance to contain man-made ionizing radiation with corporate hospitals' has indicated more than required controls in place [18]. Research studies on 'Best Practices towards Radiation Safety Measures in Government Hospitals' have shown an extraordinary level of compliance [19]. The literature review has identified a research gap for conducting a study on '*Comparative analysis of Factors Influencing Radiation Control Measures*.'

III. Research Question

Do institutions housing Diagnostic Imaging X-ray equipment (Corporate Hospitals, Government Hospitals, Chain of Diagnostic Centers and Private Diagnostic Centers) show similarity in Radiation Compliance Score?

IV. Research Objectives

To compare radiation compliance score based on the best practices recommended by the regulator (AERB) among Corporate Hospitals, Government Hospitals, Chain of Diagnostic Centers and Private Diagnostic Centers who are the consumers of X-ray equipments and analyze any significant variation exists.

V. Research Design

This Descriptive Research aims at studying the current best practices followed by the institutions housing diagnostic imaging equipment, to contain excessive ionizing radiation based on the recommendations of regulatory standards. This study has covered 25 different cities across Tamil Nadu, India and covered 451 institutions (229 Private Diagnostic Centers, 107 Chain of Diagnostic Centers, 77 Corporate hospitals, and 38 Government hospitals). This study has followed "Stratified Purposive" sampling to ensure adequate representations from the entire stratum. A structured Questionnaire with a seven-point scale (Table I) was administered to collect data from the institutions housing diagnostic imaging equipment. The researcher conducted this study for the period between April 2016 and September 2017. The instrument reliability was tested using Cronbach's Alpha, and it was calculated to be 0.992 (Acceptable threshold limit is 0.8). The sampling adequacy was estimated using Kaiser-Meyer-Olkin test and was estimated to be 0.93839 (Acceptable limit is minimum 0.6).

Table I: Research Instrument Measurement Scale

0	1	2	3	4	5	6
No Practice Exist	Marginal Presence	Moderate Presence	Significant Presence	High Presence	Very High Presence	Complete Presence

VI. Kruskal-Wallis Test

The Kruskal-Wallis test (Kruskal, & Wallis, 1952) was chosen to test the hypothesis, '*Significant difference exists in the mean ranks of compliance score between these institutions*.' A descriptive analysis (Table II) was performed to assess the normality of data based on the compliance score. The histogram on the distribution of data was constructed (Figure I).

Table II: Descriptive analysis for Normality Test

Sl. No.	Description of Variable	N	Median	Mode	Mean	Std. Dev	Skewness	Kurtosis
1	Overall	28	5	6	4.54	1.654	-0.526	-1.348
2	Private Diagnostic Centers	7	2	2	2.8	1.069	0.374	- 2.800
3	Chain of Diagnostic Centers	7	4	4	3.29	0.951	-1.678	-0.764
4	Corporate Hospitals	7	6	6	6	0	0.764	1.587
5	Government Hospitals	7	6	6	6	0	0.794	1.587

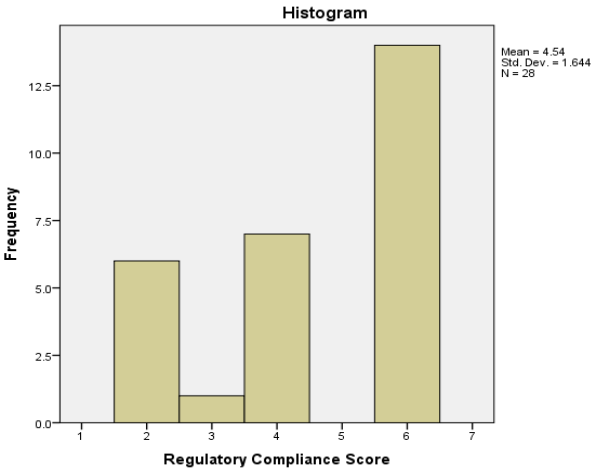

Figure I: Histogram for distribution of compliance score

It was evident from the histogram that the data distribution is not normal (bi-nodal distribution). The Skewness value estimated has shown both positive and negatively skewed data (- 1.678 and + 1.654). Kurtosis values estimated between - 2.800 and + 1.587 have described that the distribution is non-normal. Hence, the normality test results mandate the application of Kruskal-Wallis test as a statistical method for comparative analysis.

VII. Testing of Hypothesis using Kruskal-Wallis Test

The assumption on the existence of marginating variable was first tested to use the power of Kruskal-Wallis test. The marginating variable was tested with the help of the following hypothesis.

Null Hypothesis: "No marginating variance exists amongst the distribution from four (Diagnostic Centers, Chain of Diagnostic Centers, Government Hospitals, and Corporate Hospitals) groups".

Table III: Lewin's Test for Non-Parametric Statistics (ANOVA)

	Sum of Squares	df	Mean Square	F	Sig. ('P' Value)
Between Groups	862.607	3	287.536	39.807	.000
Within Groups	173.357	24	7.223		
Total	1035.964	27			

ANOVA was performed using absolute mean rank distribution values and results shown in Table III. The researcher rejected the null hypothesis based on the estimated 'P' value ('0'- zero) which is less than Alpha (0.05) value, and so it has been concluded that the variances are not roughly marginal.

VIII. Kruskal-Wallis Test

The test was conducted using SPSS (version 20), and test results of Kruskal-Wallis test have been compiled and presented in Table IV, V & VI.

Table IV: Estimation of marginating variable using Kruskal-Wallis Test

Compliance Score	Group	Group Description	Rank	Mean Rank Distribution	Absolute Mean Rank Distribution
2	1	Diagnostic Centers	3.500	2.86	.64
2	1		3.500	2.86	.64
4	1		11.000	2.86	8.14
4	1		11.000	2.86	8.14
2	1		3.500	2.86	.64
4	1		11.000	2.86	8.14
2	1		3.500	2.86	.64
3	2	Chain of Diagnostic Centers	7.000	3.29	3.71
2	2		3.500	3.29	.21
4	2		11.000	3.29	7.71
4	2		11.000	3.29	7.71
2	2		3.500	3.29	.21
4	2		11.000	3.29	7.71
4	2		11.000	3.29	7.71
6	3	Government Hospitals	21.500	6.00	15.50
6	3		21.500	6.00	15.50
6	3		21.500	6.00	15.50
6	3		21.500	6.00	15.50
6	3		21.500	6.00	15.50
6	3		21.500	6.00	15.50
6	3		21.500	6.00	15.50

6	4	Corporate Hospitals	21.500	6.00	15.50
6	4		21.500	6.00	15.50
6	4		21.500	6.00	15.50
6	4		21.500	6.00	15.50
6	4		21.500	6.00	15.50
6	4		21.500	6.00	15.50
6	4		21.500	6.00	15.50

Table V: Kruskal-Wallis Test Summary

	Type of Institutions	N	Mean Rank
Regulatory Compliance Score	Diagnostic centers	7	6.71
	Chain of Diagnostic Centers	7	8.29
	Government Hospitals	7	21.50
	Corporate Hospitals	7	21.50
	Total	28	6.71

Table VI: Test Statistics

	Regulatory Compliance Score
Chi-Square	23.988
df	3
Asymp. Sig.	.000

From the Kruskal-Wallis test results, the estimated 'P' value is '0" (Zero) which is less than the alpha value (0.05), and hence the hypothesis of '*There will be a significant difference in compliance score between these groups*' has been accepted. There is a significant difference between mean ranks of Private Diagnostic Centers and Chain of Diagnostic Centers. However, the mean rank estimated for Government hospitals and corporate hospitals are found to be the same. The results though have shown a significant difference between the groups; it did not point out which group contributes notable variance. Hence the effect size was estimated using Chi-Square value (Chi-Square Value / n -1 *100) and found to be 85.37 percent. This predicts 85.37 percent variability in mean rank is affected by the type of institutions.

The following groups formed to repeat the Kruskal-Wallis test to find out the group (s) that statistically significant from each other, and results are summarized:

1. Between Diagnostic Centers and Chain of Diagnostic Centers (Table VII & VIII).
2. Between Chain of Diagnostic Centers and Government Hospitals (Table IX & X).
3. Between Government hospitals and Corporate Hospitals (Table XI & XII).

Table VII: Kruskal-Wallis Test - Diagnostic Centers Vs. Chain of Diagnostic Centers

	Type of Institutions	N	Mean Rank
Regulatory Compliance Score	Diagnostic centers	7	6.71
	Chain of Diagnostic Centers	7	8.29
	Total	14	

Table VIII: Test Statistics

	Regulatory Compliance Score
Chi-Square	0.617
df	1
Asymp. Sig.	.432

The mean rank between Chain of Diagnostic Centers and Diagnostic Centers has been found to be statistically insignificant from the results of Kruskal-Wallis test with an estimated 'P' value of 0.432, which is higher than the alpha value 0.05. Furthermore, Diagnostic centers and Chain of diagnostic centers attribute 4.41 percent of the variability in the mean rank.

Table IX: Kruskal-Wallis Test - Chain of Diagnostic Centers Vs. Government Hospitals

	Type of Institutions	N	Mean Rank
Regulatory Compliance Score	Chain of Diagnostic centers	7	4.00
	Government Hospitals	7	11.00
	Total	14	

Table X: Test Statistics

	Regulatory Compliance Score
Chi-Square	11.492
df	1
Asymp. Sig.	0.001

The mean rank between Diagnostic Centers and Government hospitals has been found to be statistically significant from the results of Kruskal-Wallis test with an estimated 'P' of 0.001, which is less than the alpha value 0.05. However, Diagnostic centers and Government hospitals accredit 82.09 percent of the variability in mean ranks.

Table XI: Kruskal-Wallis Test - Corporate Hospitals Vs. Government Hospitals

	Type of Institutions	N	Mean Rank
Regulatory Compliance Score	Corporate Hospitals	7	7.50
	Government Hospitals	7	7.50
	Total	14	

Table XII: Test Statistics

	Regulatory Compliance Score
Chi-Square	0.000
df	1
Asymp. Sig.	1.000

The mean rank between corporate hospitals and Government hospitals has been found to be statistically insignificant from the results of Kruskal-Wallis test with an estimated 'P' of 1.00, which is higher than the alpha value 0.05. The 'Zero' chi-square value indicates that there is no significant difference in mean rank between Government hospitals and Corporate hospitals.

IX. Conclusion

It was evident from the analysis that there is a significant difference in regulatory compliance score between the groups of institutions compared. The mean compliance score of Private Diagnostic centers (2.8, Table I) enunciates that dissemination of radiation containment standards into best practices was found to be marginally less than significant levels. The Chain of Diagnostic centers have established practices whose compliance was closely above sufficient levels (mean score 3.29, Table. I). The Private Diagnostic centers and Chain of Diagnostic centers have established requisite practices to contain excessive ionizing radiation, leaving ample of improvement opportunities.

The Government and Corporate hospitals have established superior compliance to regulatory policies and fully translated standard requirements into more than adequate best practices. They are on par with each other and well supported by the test results that both the institutions have 'complete presence' of practices that ensure regulatory compliance. This study recommends further research work on '*Effective dose absorption between refurbished CT and new CT machine.*'

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